National Clinical Guideline Centre

Final Full Guideline

Stroke Rehabilitation

Long term rehabilitation after stroke

Clinical guideline 162

Methods, evidence and recommendations

June 2013

Final

Commissioned by the National Institute for Health and Care Excellence

Update information

NICE's original guidance on stroke rehabilitation in adults was published in 2013. In 2023, we updated and replaced this guideline, adding new sections on:

- telerehabilitation
- hearing
- fatigue
- mouth care
- spasticity

We also updated the sections on:

- transfer of care from hospital to community, including early supported discharge
- intensity of stroke rehabilitation
- vision
- swallowing
- movement
- shoulder pain
- self-care
- long-term health and social support.

See the NICE website for the guideline recommendations and the evidence reviews for the 2023 version of this guideline. This document preserves evidence reviews and committee discussions for areas of the guideline that were not updated in 2023.

Disclaimer
Healthcare professionals are expected to take NICE clinical guidelines fully into account when exercising their clinical judgement. However, the guidance does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of each patient, in consultation with the patient and/or their guardian or carer.

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National Institute for Health and Care Excellence

Contents

Guideline development group members

Name	Organisation
Dr. Diane Playford (Chair)	Reader in neurological rehabilitation UCL Institute of Neurology Honorary Consultant Neurologist National Hospital for Neurology and Neurosurgery, UCLH NHS Foundation Trust
Dr. Khalid Ali	Senior Lecturer in Geriatrics Brighton and Sussex Medical School
Mr. Martin Bird	Carer member
Mr. Robin Cant	Patient member
Ms. Sandra Chambers	Clinical Specialist Stroke and Neurorehabilitation, Physiotherapy Department, Guy's and St. Thomas' Hospital NHS Foundation Trust
Ms. Louise Clark	Trainee Consultant Practitioner in Neurology (Stroke) NHS South Central Senior Occupational Therapist specialising in Stroke
Dr. Avril Drummond	Deputy Director, Trent Local Research Network for Stroke (Resigned from the Guideline Development Group in October 2012)
Prof. Anne Forster	Professor of Stroke Rehabilitation Institute of Health Sciences, University of Leeds and Bradford Institute for Health Research (Resigned from the Guideline Development Group in March 2013)
Dr. Kathryn Head	Principal Speech and Language Therapist Stroke service, Cwm Taf Health Board, South Wales
Ms. Pamela Holmes	Representative Social Care Institute for Excellence
Ms. Helen E. Hunter	Clinical Specialist Neurophysiotherapist Northumberland Care Trust
Dr. Najma Khan-Bourne	Consultant Clinical Neuropsychologist Clinical Lead for Neuropsychological Neurorehabilitation Kings College Hospital, Kings College Hospital NHS Foundation Trust
Dr. Keith MacDermott	General Practitioner (Retired from General Practice in April 2010) Drs. Price and partners, York
Dr. Rory O'Connor	Honorary Consultant in Rehabilitation Medicine Community Rehabilitation Unit, Leeds Community Healthcare NHS Trust Leeds Honorary Consultant in Rehabilitation Medicine National Demonstration Centre in Rehabilitation, Leeds Teaching Hospitals NHS Trust, Leeds
Ms. Sue Thelwell	Stroke Services Co-ordinator University Hospitals Coventry and Warwickshire NHS Trust

Co-optees/Expert Advisors

Name	Organisation
Ms. Julia Parnaby	Head of Stroke Information Services Stroke Association
Ms. Carole Pound	Researcher - aphasia therapy and support services Centre for Research and Rehabilitation, Brunel University
Dr. Fiona Rowe	Senior Lecturer in Orthoptics University of Liverpool
Mr. Ronald Barney White	Senior Orthotist Sandwell and West Birmingham Hospitals NHS Trust

NCGC Staff members on the guideline development group

Name	Role
Ms. Gill Ritchie	Guideline Lead
Ms. Tamara Diaz	Project Manager
Ms. Lina Gulhane	Joint Head of Information Science
Dr. Katharina Dworzynski	Senior Research Fellow
Dr. Jonathan Nyong	Research Fellow
Ms. Elisabetta Fenu	Senior Health Economist

Dr. Angela Cooper	Senior Research Fellow	until July 2010
Dr. Pauline Turner	Research Fellow	until August 2010
Dr. Antonia Morga	Health Economist	until April 2011
Lola Adedokun	Health Economist	until June 2012
Dr. Grammati Sarri	Senior Research Fellow	until July 2012
Ms. Kate Lovibond	Senior Health Economist	until August 2012

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The development of this guideline was greatly assisted by the following people:

NCGC:	Role
Serena Carville	Senior Research Fellow/Project Manager
Sharangini Rajesh	Research Fellow
Jaymeeni Solanki	Project coordinator
Rosa Lau	Research Fellow
Ralph Hughes	Health Economist
Philippe Laramee	Health Economist
Richard Whitome	Information Scientist
David Wonderling	Head of Health Economics

External	Role
Charlie Davie	Stroke Lead, UCL Partners
Jacoby Patterson	Research Fellow
Mirek Skrypak	Stroke REDS team coordinator, NHS Camden
Claire Turner	NICE Commissioning Manager from July 2010
Sarah Willett	NICE Commissioning manager until July 2010

1 Introduction

Stroke is a major health problem in the UK. Each year in England, approximately 110,000 people [230], in Wales 11,000 and in Northern Ireland 4,000 people have a first or recurrent stroke [250]. Most people survive a first stroke, but often have significant morbidity. More than 900,000 people in England are living with the effects of stroke. Stroke mortality rates in the UK have been falling steadily since the late 1960s[25]. The development of stroke units following the publication of the Stroke Unit Trialists Collaboration meta-analysis of stroke unit care [1], and the further reorganisation of services following the advent of thrombolysis have resulted in further significant improvements in mortality and morbidity from stroke (as documented in the National Sentinel Audit for Stroke [123]). However, the burden of stroke may increase in the future as a consequence of the ageing population.

Despite improvements in mortality and morbidity, stroke survivors need access to effective rehabilitation services. Over 30% of people have persisting disability and they need access to stroke services long term. Stroke rehabilitation is a multidimensional process, which is designed to facilitate restoration of, or adaptation to, the loss of physiological or psychological function when reversal of the underlying pathological process is incomplete. Rehabilitation aims to enhance functional activities and participation in society and thus improve quality of life.

A stroke rehabilitation service comprises a multidisciplinary team of people who work together towards goals for each patient, involve and educate the patient and family, have relevant knowledge and skills to help address most common problems faced by their patients[276] Key aspects of rehabilitation care include multidisciplinary assessment, identification of functional difficulties and their measurement, treatment planning through goal setting, delivery of interventions which may either effect change or support the individual in managing persisting change, and evaluation of effectiveness.

Assessment is typically undertaken using the World Health Organisation (WHO) International Classification of Functioning, Disability and Health (ICF) which provides a bio-psychosocial model of disability. As well as supporting comprehensive assessment the ICF can be used in goal setting & treatment planning and monitoring, as well as outcome measurement. Treatments are largely delivered via physiotherapists, occupational therapists, speech and language therapists, nurses and psychologists. Other components of rehabilitation include the learning of new skills to circumvent those lost; adaptation to loss by both the patient and family; the application of new technologies, appliances and environmental modifications; and the development of new service delivery systems. The rehabilitation process aims to maximise the participation of the patient in his or her social setting, including supporting people to establish roles and occupations, and minimise the pain and distress experienced by the patient and their family carers[276].

Clear standards exist for stroke rehabilitation, for instance as described both in the National Clinical Guideline for Stroke developed by the Intercollegiate Stroke Working Party [122]. These are reflected in the NICE quality standards [189] and the National Stroke Strategy [61]. Overall there is little doubt that the rehabilitation approach is effective; what individual interventions should take place within this structure is less clear.

Advances in the neurosciences including greater understanding of the mechanisms of impairment will lead to novel treatments. There is a wealth of evidence suggesting that central nervous system reorganisation underlies much of the improvement in impairment that is frequently seen. Experiments show that some regions in the normal adult brain, particularly the cortex, have the capacity to change structure and consequently function in response to environmental change, a process described as plasticity. In addition functionally relevant adaptive changes have been demonstrated following focal damage to the brain. It is suggested that rehabilitation therapies interacts with these plastic changes, thus reducing impairment via activity dependent plastic

change.[280] Examples of such therapies already exist in rehabilitation practice such as upper or lower limb sensorimotor function by task-related training using constraint induced therapy [173], treadmill training [109], and prism adaptation (to reverse visual neglect) [87,109].

The aim of this guideline development group was to review the structure, processes and interventions currently used in rehabilitation care, and to evaluate whether they improve outcomes for people with stroke. Such studies are complex and research methodologies need to be robust. Evaluation of clinical effectiveness needs studies that have robust theoretical underpinnings, capture changes that are relevant to the treatment evaluated and reflect what is important to patients, and be large enough to allow reliable data interpretation. This guideline reviews some of the available interventions that can be used in stroke rehabilitation, and highlights where there are gaps in the evidence. It is not intended to be comprehensive.

All interventions should take place in the context of a comprehensive stroke pathway which recognises that early management, while critical, is a component of a process which aims to ameliorate the long term consequences of living with stroke for individuals and their families and to enable them to live at home, able to participate in as many activities as they are able. At the point of discharge the person who has had a stroke may need support from a range of other agencies such as housing, Jobcentre Plus, social services and stroke voluntary organisations. Randomised controlled trial evidence, although the gold standard for intervention studies may not be available or appropriate for examining rehabilitation processes. A modified Delphi survey was conducted to obtain formal consensus around areas such as service delivery and care planning. It needs to be recognised that even where the evidence base is clear, rehabilitation interventions need to be targeted and relevant to the individual. Some individuals may decline treatment which health care professionals see as important. In such circumstances issues such as capacity and consent need to be considered [108].

2 Development of the guideline

2.1 What is a NICE clinical guideline?

NICE clinical guidelines are recommendations for the care of individuals in specific clinical conditions or circumstances within the NHS – from prevention and self-care through primary and secondary care to more specialised services. We base our clinical guidelines on the best available research evidence, with the aim of improving the quality of health care. We use predetermined and systematic methods to identify and evaluate the evidence relating to specific review questions.

NICE clinical guidelines can:

- provide recommendations for the treatment and care of people by health professionals
- be used to develop standards to assess the clinical practice of individual health professionals
- be used in the education and training of health professionals
- help patients to make informed decisions
- improve communication between patient and health professional

While guidelines assist the practice of healthcare professionals, they do not replace their knowledge and skills.

We produce our guidelines using the following steps:

- Guideline topic is referred to NICE from the Department of Health
- Stakeholders register an interest in the guideline and are consulted throughout the development process
- The scope is prepared by the National Clinical Guideline Centre (NCGC)
- The NCGC establishes a guideline development group
- A draft guideline is produced after the group assesses the available evidence and makes recommendations
- There is a consultation on the draft guideline
- The final guideline is produced

The NCGC and NICE produce a number of versions of this guideline:

- the full guideline contains all the recommendations, plus details of the methods used and the underpinning evidence
- the NICE guideline lists the recommendations
- the NICE Pathway is an online tool for health professionals that brings together the recommendations from this guidance and all related NICE guidance.
- information for the public ('understanding NICE guidance' or UNG) is written using suitable language for people without specialist medical knowledge

This version is the full version. The other versions can be downloaded from NICE at www.nice.org.uk

2.2 Remit

NICE received the remit for this guideline from the Department of Health. They commissioned the NCGC to produce the guideline.

The remit for this guideline is: to produce a joint clinical and social care guideline on the long-term rehabilitation and support of stroke patients.

2.3 Who developed this guideline?

A multidisciplinary Guideline Development Group (GDG) comprising professional group members and consumer representatives of the main stakeholders developed this guideline (see section on Guideline Development Group Membership and acknowledgements).

The National Institute for Health and Clinical Excellence funds the National Clinical Guideline Centre (NCGC) and thus supported the development of this guideline. The GDG was convened by the NCGC and chaired by Dr Diane Playford in accordance with guidance from the National Institute for Health and Clinical Excellence (NICE).

The group met approximately every 5 weeks during the development of the guideline. At the start of the guideline development process all GDG members declared interests including consultancies, fee-paid work, share-holdings, fellowships and support from the healthcare industry. At all subsequent GDG meetings, members declared arising conflicts of interest, which were also recorded (Appendix [C]).

Members were either required to withdraw completely or for part of the discussion if their declared interest made it appropriate. The details of declared interests and the actions taken are shown in Appendix [C].

Staff from the NCGC provided methodological support and guidance for the development process. The team working on the guideline included a project manager, systematic reviewers, health economists and information scientists. They undertook systematic searches of the literature, appraised the evidence, conducted meta-analysis and cost effectiveness analysis where appropriate and drafted the guideline in collaboration with the GDG.

2.4 What this guideline covers

The guideline covers adults and young people 16 or older who have had a stroke and have continuing impairment (2 weeks or more post stroke), limited activity or participation restriction.

The clinical areas covered included: therapies to improve physical, cognitive and speech functions, activities of daily living and vocational rehabilitation, interventions to address dysphagia and visual field loss, information and support for patients and carers, early supported discharge and intensity of rehabilitation therapy. The interventions considered and the subsequent recommendations made are not setting specific and include health or social care services.

For further details please refer to the scope in Appendix A and review questions in Appendix E.

2.5 What this guideline does not cover

Children under 16 years and people who had had a transient ischaemic attack were not included. The guideline did not consider primary or secondary prevention of stroke, acute stroke or assessment for rehabilitation.

2.6 Relationships between the guideline and other NICE guidance

Related NICE Interventional Procedures:

Electrical stimulation for drop foot of central neurological origin. NICE interventional procedure guidance 278 (2009). Available from www.nice.org.uk/guidance/IPG278

Related NICE Clinical Guidelines:

Depression in adults (update). NICE clinical guideline CG90 (2009). Available from: http://publications.nice.org.uk/depression-in-adults-cg90.

Depression in adults with a chronic physical health problem: Treatment and management. NICE clinical guideline CG91 (2009). Available from: http://publications.nice.org.uk/depression-in-adults-with-a-chronic-physical-health-problem-cg91.

Faecal incontinence: The management of faecal incontinence in adults NICE clinical guideline CG49 (2007). Available from: http://publications.nice.org.uk/faecal-incontinence-cg49.

Falls: the assessment and prevention of falls in older people. NICE clinical guideline CG21 (2004) http://publications.nice.org.uk/falls-cg21.

Generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults: Management in primary, secondary and community care. NICE clinical guideline CG113 (2011). Available from: http://publications.nice.org.uk/generalised-anxiety-disorder-and-panic-disorder-with-or-without-agoraphobia-in-adults-cg113.

Neuropathic pain: The pharmacological management of neuropathic pain in adults in non-specialist settings NICE clinical guideline CG96 (2010). http://publications.nice.org.uk/neuropathic-pain-cg96.

Nutrition support in adults: Oral nutrition support, enteral tube feeding and parenteral nutrition. NICE clinical guideline CG32 (2006). Available from: http://publications.nice.org.uk/nutrition-support-in-adults-cg32.

Patient experience in adult NHS services: improving the experience of care for people using adult NHS services. NICE clinical guideline CG138 (2012) http://publications.nice.org.uk/patient-experience-in-adult-nhs-services-improving-the-experience-of-care-for-people-using-adult-cg138.

Stroke: Diagnosis and initial management of acute stroke and transient ischaemic attack (TIA). NICE clinical guideline CG68 (2008). Available from: http://publications.nice.org.uk/stroke-cg68.

Urinary incontinence in neurological disease: management of lower urinary tract dysfunction in neurological disease. NICE clinical guideline CG148 (2012). Available from: http://guidance.nice.org.uk/CG148.

Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence. NICE clinical guideline CG76 (2009). Available from: http://www.nice.org.uk/CG76

Lipid modification: Cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease. NICE clinical guideline CG67 (2008). Available from: http://www.nice.org.uk/CG67.

Hypertension: clinical management of primary hypertension in adults. NICE clinical guideline CG127 (2011): Available from: http://guidance.nice.org.uk/CG127.

Type2 Diabetes: the management of type 2 diabetes (update). NICE clinical guideline CG87 (2009): Available from: http://www.nice.org.uk/CG87.

Atrial fibrillation. NICE clinical guideline CG36 (2006): Available from: http://www.nice.org.uk/CG36

Related NICE Public Health Guidance:

Management of long-term sickness and incapacity for work: Guidance for primary care and employers on the management of long term sickness and incapacity. NICE public health guidance 19 (2009). Available from: www.nice.org.uk/guidance/PH19.

NICE Related Guidance currently in development:

Falls (update) NICE clinical guideline (publication expected June 2013).

Lipid modification (update). NICE clinical guideline (publication TBC).

Neuropathic pain: pharmacological management in adults in non-specialist settings. NICE clinical guideline (publication expected August 2013).

Type 2 diabetes NICE clinical guideline (publication TBC).

Oral health: in nursing and residential care NICE public health guidance (publication TBC).

Workplace health: employees with chronic diseases and long-term conditions NICE public health guidance (publication TBC).

3 Guideline summary

3.1 Key priorities for implementation

The GDG identified key priorities for implementation. They selected recommendations that would:

- Have a high impact on outcomes that are important to patients
- Have a high impact on reducing variation in care and outcomes
- Lead to a more efficient use of NHS resources
- Promote patient choice

In doing this the GDG also considered which recommendations were particularly likely to benefit from implementation support. The considered whether a recommendation:

- Requires changes in service delivery
- Requires retraining of professionals or the development of new skills and competencies
- Affects and needs to be implemented across various agencies or settings
- May be viewed as potentially contentious or difficult to implement for other reasons

The following recommendations have been identified as priorities for implementation.

3.1.1 Stroke units

1. People with disability after stroke should receive rehabilitation in a dedicated stroke inpatient unit and subsequently from a specialist stroke team within the community.

3.1.2 The core multidisciplinary stroke team

2. A core multidisciplinary stroke rehabilitation team should comprise the following professionals with expertise in stroke rehabilitation:
    - consultant physicians
    - nurses
    - physiotherapists
    - occupational therapists
    - speech and language therapists
    - clinical psychologists
    - rehabilitation assistants
    - social workers.

3.1.3 Health and social care interface

3. Health and social care professionals should work collaboratively to ensure a social care assessment is carried out promptly, where needed, before the person with stroke is transferred from hospital to the community. The assessment should:
    - identify any ongoing needs of the person and their family or carer, for example, access to benefits, care needs, housing, community participation, return to work, transport and access to voluntary services
    - be documented and all needs recorded in the person's health and social care plan, with a copy provided to the person with stroke.

3.1.4 Transfer of care from hospital to community

4. Offer early supported discharge to people with stroke who are able to transfer from bed to chair independently or with assistance, as long as a safe and secure environment can be provided.

3.1.5 Setting goals for rehabilitation

5. Ensure that goal-setting meetings during stroke rehabilitation:
   - are timetabled into the working week
   - involve the person with stroke and, where appropriate, their family or carer in the discussion.

3.1.6 Intensity of stroke rehabilitation

6. Offer initially at least 45 minutes of each relevant stroke rehabilitation therapy for a minimum of 5 days per week to people who have the ability to participate, and where functional goals can be achieved. If more rehabilitation is needed at a later stage, tailor the intensity to the person's needs at that time[a].

3.1.7 Cognitive functioning

7. Screen people after stroke for cognitive deficits. Where a cognitive deficit is identified, carry out a detailed assessment using valid, reliable and responsive tools before designing a treatment programme.

3.1.8 Emotional functioning

8. Assess emotional functioning in the context of cognitive difficulties in people after stroke. Any intervention chosen should take into consideration the type or complexity of the person's neuropsychological presentation and relevant personal history.

3.1.9 Swallowing

9. Offer swallowing therapy at least 3 times a week to people with dysphagia after stroke who are able to participate, for as long as they continue to make functional gains. Swallowing therapy could include compensatory strategies, exercises and postural advice.

3.1.10 Return to work

10. Return-to-work issues should be identified as soon as possible after the person's stroke, reviewed regularly and managed actively. Active management should include:
    - identifying the physical, cognitive, communication and psychological demands of the job (for example, multi-tasking by answering emails and telephone calls in a busy office)
    - identifying any impairments on work performance (for example, physical limitations, anxiety, fatigue preventing attendance for a full day at work, cognitive impairments preventing multi-tasking, and communication deficits)
    - tailoring an intervention (for example, teaching strategies to support multi-tasking or memory difficulties, teaching the use of voice-activated software for people with difficulty typing, and delivery of work simulations)
    - educating about the Equality Act 2010[b] and support available (for example, an access to work scheme)
    - workplace visits and liaison with employers to establish reasonable accommodations, such as provision of equipment and graded return to work.

[a] Intensity of therapy for dysphagia, provided as part of speech and language therapy is addressed in recommendation 58.

[b] HM Government (2010) Equality Act [online]

3.1.11 Long-term health and social support

- Review the health and social care needs of people after stroke and the needs of their carers at 6 months and annually thereafter. These reviews should cover participation and community roles to ensure that people's goals are addressed.

3.2 Full list of recommendations

1. People with disability after stroke should receive rehabilitation in a dedicated stroke inpatient unit and subsequently from a specialist stroke team within the community.
2. An inpatient stroke rehabilitation service should consist of the following:
    - a dedicated stroke rehabilitation environment
    - a core multidisciplinary team (see recommendation 3) who have the knowledge, skills and behaviours to work in partnership with people with stroke and their families and carers to manage the changes experienced as a result of a stroke.
    - access to other services that may be needed, for example:
    - continence advice
    - dietetics
    - electronic aids (for example, remote controls for doors, lights and heating, and communication aids)
    - liaison psychiatry
    - orthoptics
    - orthotics
    - pharmacy
    - podiatry
    - wheelchair services
    - a multidisciplinary education programme.
3. A core multidisciplinary stroke rehabilitation team should comprise the following professionals with expertise in stroke rehabilitation:
    - consultant physicians
    - nurses
    - physiotherapists
    - occupational therapists
    - speech and language therapists
    - clinical psychologists
    - rehabilitation assistants
    - social workers.
4. Throughout the care pathway, the roles and responsibilities of the core multidisciplinary stroke rehabilitation team should be clearly documented and communicated to the person and their family or carer.

5. Members of the core multidisciplinary stroke team should screen the person with stroke for a range of impairments and disabilities, in order to inform and direct further assessment and treatment.

6. Health and social care professionals should work collaboratively to ensure a social care assessment is carried out promptly, where needed, before the person with stroke is transferred from hospital to the community. The assessment should:

   - identify any ongoing needs of the person and their family or carer, for example, access to benefits, care needs, housing, community participation, return to work, transport and access to voluntary services.
   - be documented and all needs recorded in the person's health and social care plan, with a copy provided to the person with stroke.

7. Offer training in care (for example, in moving and handling and helping with dressing) to family members or carers who are willing and able to be involved in supporting the person after their stroke.

   - Review family members' and carers' training and support needs regularly (as a minimum at the person's 6-month and annual reviews), acknowledging that these needs may change over time.

8. Offer early supported discharge to people with stroke who are able to transfer from bed to chair independently or with assistance, as long as a safe and secure environment can be provided.

9. Early supported discharge should be part of a skilled stroke rehabilitation service and should consist of the same intensity of therapy and range of multidisciplinary skills available in hospital. It should not result in a delay in delivery of care.

10. Hospitals should have systems in place to ensure that:

    - people after stroke and their families and carers (as appropriate) are involved in planning for transfer of care, and carers receive training in care (for example, in moving and handling and helping with dressing)
    - people after stroke and their families and carers feel adequately informed, prepared and supported
    - GPs and other appropriate people are informed before transfer of care
    - an agreed health and social care plan is in place, and the person knows whom to contact if difficulties arise
    - appropriate equipment (including specialist seating and a wheelchair if needed) is in place at the person's residence, regardless of setting.

11. Before transfer from hospital to home or to a care setting, discuss and agree a health and social care plan with the person with stroke and their family or carer (as appropriate), and provide this to all relevant health and social care providers.

12. Before transfer of care from hospital to home for people with stroke:

    - establish that they have a safe and enabling home environment, for example, check that appropriate equipment and adaptations have been provided and that carers are supported to facilitate independence, and

- undertake a home visit with them unless their abilities and needs can be identified in other ways, for example, by demonstrating independence in all self-care activities, including meal preparation, while in the rehabilitation unit.

13. On transfer of care from hospital to the community, provide information to all relevant health and social care professionals and the person with stroke. This should include:
    - a summary of rehabilitation progress and current goals
    - diagnosis and health status
    - functional abilities (including communication needs)
    - care needs, including washing, dressing, help with going to the toilet and eating
    - psychological (cognitive and emotional) needs
    - medication needs (including the person's ability to manage their prescribed medications and any support they need to do so)
    - social circumstances, including carers' needs
    - mental capacity regarding the transfer decision
    - management of risk, including the needs of vulnerable adults
    - plans for follow-up, rehabilitation and access to health and social care and voluntary sector services.
14. Ensure that people with stroke who are transferred from hospital to care homes receive assessment and treatment from stroke rehabilitation and social care services to the same standards as they would receive in their own homes.
15. Local health and social care providers should have standard operating procedures to ensure the safe transfer and long-term care of people after stroke, including those in care homes. This should include timely exchange of information between different providers using local protocols.
16. After transfer of care from hospital, people with disabilities after stroke (including people in care homes) should be followed up within 72 hours by the specialist stroke rehabilitation team for assessment of patient-identified needs and the development of shared management plans.
17. Provide advice on prescribed medications for people after stroke in line with recommendations in Medicines adherence (NICE clinical guideline 76).
18. On admission to hospital, to ensure the immediate safety and comfort of the person with stroke, screen them for the following and, if problems are identified, start management as soon as possible:
    - orientation
    - positioning, moving and handling
    - swallowing
    - transfers (for example, from bed to chair)
    - pressure area risk
    - continence

- communication, including the ability to understand and follow instructions and to convey needs and wishes
- nutritional status and hydration (follow the recommendations in Stroke [NICE clinical guideline 68] and Nutrition support in adults [NICE clinical guideline 32]).

19. Perform a full medical assessment of the person with stroke, including cognition (attention, memory, spatial awareness, apraxia, perception), vision, hearing, tone, strength, sensation and balance.
20. A comprehensive assessment of a person with stroke should take into account:
    - their previous functional abilities
    - impairment of psychological functioning (cognitive, emotional and communication)
    - impairment of body functions, including pain
    - activity limitations and participation restrictions
    - environmental factors (social, physical and cultural).
21. Information collected routinely from people with stroke using valid, reliable and responsive tools should include the following on admission and discharge:
    - National Institutes of Health Stroke Scale
    - Barthel Index.
22. Information collected from people with stroke using valid, reliable and responsive tools should be fed back to the multidisciplinary team regularly.
23. Take into consideration the impact of the stroke on the person's family, friends and/or carers and, if appropriate, identify sources of support.
24. Inform the family members and carers of people with stroke about their right to have a carer's needs assessment.
25. Ensure that people with stroke have goals for their rehabilitation that:
    - are meaningful and relevant to them
    - focus on activity and participation
    - are challenging but achievable
    - include both short-term and long-term elements.
26. Ensure that goal-setting meetings during stroke rehabilitation:
    - are timetabled into the working week
    - involve the person with stroke and, where appropriate, their family or carer in the discussion.
27. Ensure that during goal-setting meetings, people with stroke are provided with:
    - an explanation of the goal-setting process
    - the information they need in a format that is accessible to them
    - the support they need to make decisions and take an active part in setting goals.

28. Give people copies of their agreed goals for stroke rehabilitation after each goal-setting meeting.

29. Review people's goals at regular intervals during their stroke rehabilitation.

30. Provide information and support to enable the person with stroke and their family or carer (as appropriate) to actively participate in the development of their stroke rehabilitation plan.

31. Stroke rehabilitation plans should be reviewed regularly by the multidisciplinary team. Time these reviews according to the stage of rehabilitation and the person's needs.

32. Documentation about the person's stroke rehabilitation should be individualised, and should include the following information as a minimum:

    - basic demographics, including contact details and next of kin
    - diagnosis and relevant medical information
    - list of current medications, including allergies
    - standardised screening assessments (see recommendation 18)
    - the person's rehabilitation goals
    - multidisciplinary progress notes
    - a key contact from the stroke rehabilitation team (including their contact details) to coordinate the person's health and social care needs
    - discharge planning information (including accommodation needs, aids and adaptations)
    - joint health and social care plans, if developed
    - follow-up appointments.

33. Offer initially at least 45 minutes of each relevant stroke rehabilitation therapy for a minimum of 5 days per week to people who have the ability to participate, and where functional goals can be achieved. If more rehabilitation is needed at a later stage, tailor the intensity to the person's needs at that time[c].

34. Consider more than 45 minutes of each relevant stroke rehabilitation therapy 5 days per week for people who have the ability to participate and continue to make functional gains, and where functional goals can be achieved.

35. If people with stroke are unable to participate in 45 minutes of each rehabilitation therapy, ensure that therapy is still offered 5 days per week for a shorter time at an intensity that allows them to actively participate.

36. Working with the person with stroke and their family or carer, identify their information needs and how to deliver them, taking into account specific impairments such as aphasia and cognitive impairments. Pace the information to the person's emotional adjustment.

37. Provide information about local resources (for example, leisure, housing, social services and the voluntary sector) that can help to support the needs and priorities of the person with stroke and their family or carer.

[c] Intensity of therapy for dysphagia, provided as part of speech and language therapy is addressed in recommendation 58.

38. Review information needs at the person's 6-month and annual stroke reviews and at the start and completion of any intervention period.

39. NICE has produced guidance on the components of good patient experience in adult NHS services. Follow the recommendations in Patient experience in adult NHS services (NICE clinical guideline 138) [d].

40. Screen people after stroke for cognitive deficits. Where a cognitive deficit is identified, carry out a detailed assessment using valid, reliable and responsive tools before designing a treatment programme.

41. Provide education and support for people with stroke and their families and carers to help them understand the extent and impact of cognitive deficits after stroke, recognising that these may vary over time and in different settings.

42. Assess the effect of visual neglect after stroke on functional tasks such as mobility, dressing, eating and using a wheelchair, using standardised assessments and behavioural observation.

43. Use interventions for visual neglect after stroke that focus on the relevant functional tasks, taking into account the underlying impairment. For example:

    - interventions to help people scan to the neglected side, such as brightly coloured lines or highlighter on the edge of the page
    - alerting techniques such as auditory cues
    - repetitive task performance such as dressing
    - altering the perceptual input using prism glasses.

44. Assess memory and other relevant domains of cognitive functioning (such as executive functions) in people after stroke, particularly where impairments in memory affect everyday activity.

45. Use interventions for memory and cognitive functions after stroke that focus on the relevant functional tasks, taking into account the underlying impairment. Interventions could include:

    - increasing awareness of the memory deficit
    - enhancing learning using errorless learning and elaborative techniques (making associations, use of mnemonics, internal strategies related to encoding information such as 'preview, question, read, state, test')
    - external aids (for example, diaries, lists, calendars and alarms)
    - environmental strategies (routines and environmental prompts).

46. Assess attention and cognitive functions in people after stroke using standardised assessments. Use behavioural observation to evaluate the impact of the impairment on functional tasks.

47. Consider attention training for people with attention deficits after stroke.

48. Use interventions for attention and cognitive functions after stroke that focus on the relevant functional tasks. For example, use generic techniques such as managing the environment and providing prompts relevant to the functional task.

[d] For recommendations on continuity of care and relationships see section 1.4 and for recommendations on enabling patients to actively participate in their care see section 1.5.

49. Assess emotional functioning in the context of cognitive difficulties in people after stroke. Any intervention chosen should take into consideration the type or complexity of the person's neuropsychological presentation and relevant personal history.
50. Support and educate people after stroke and their families and carers, in relation to emotional adjustment to stroke, recognising that psychological needs may change over time and in different settings.
51. When new or persisting emotional difficulties are identified at the person's 6-month or annual stroke reviews, refer them to appropriate services for detailed assessment and treatment.
52. Manage depression or anxiety in people after stroke who have no cognitive impairment in line with recommendations in Depression in adults with a chronic physical health problem (NICE clinical guideline 91) and Generalised anxiety disorder (NICE clinical guideline 113).
53. Screen people after stroke for visual difficulties.
54. Offer eye movement therapy to people who have persisting hemianopia after stroke and who are aware of the condition.
55. When advising people with visual problems after stroke about driving, consult the Driver and Vehicle Licensing Agency (DVLA) regulations.
56. Refer people with persisting double vision after stroke for formal orthoptic assessment.
57. Assess swallowing in people after stroke in line with recommendations in Stroke (NICE clinical guideline 68).
58. Offer swallowing therapy at least 3 times a week to people with dysphagia after stroke who are able to participate, for as long as they continue to make functional gains. Swallowing therapy could include compensatory strategies, exercises and postural advice.
59. Ensure that effective mouth care is given to people with difficulty swallowing after stroke, in order to decrease the risk of aspiration pneumonia.
60. Healthcare professionals with relevant skills and training in the diagnosis, assessment and management of swallowing disorders should regularly monitor and reassess people with dysphagia after stroke who are having modified food and liquid until they are stable (this recommendation is from Nutrition support in adults [NICE clinical guideline 32]).
61. Provide nutrition support to people with dysphagia in line with recommendations in Nutrition support in adults (NICE clinical guideline 32) and Stroke (NICE clinical guideline 68).
62. Screen people after stroke for communication difficulties within 72 hours of onset of stroke symptoms.
63. Each stroke rehabilitation service should devise a standardised protocol for screening for communication difficulties in people after stroke.
64. Provide appropriate information, education and training to the multidisciplinary stroke team to enable them to support and communicate effectively with the person with communication difficulties and their family or carer.
65. Speech and language therapy for people with stroke should be led and supervised by a specialist speech and language therapist working

collaboratively with other appropriately trained people – for example, speech and language therapy assistants, carers an friends, and members of the voluntary sector.

66. Provide opportunities for people with communication difficulties after stroke to have conversation and social enrichment with people who have the training, knowledge, skills and behaviours to support communication. This should be in addition to the opportunities provided by families, carers and friends.

67. Speech and language therapists should assess people with limited functional communication after stroke for their potential to benefit from using a communication aid or other technologies (for example, home-based computer therapies or smartphone applications).

68. Provide communication aids for those people after stroke who have the potential to benefit, and offer training in how to use them.

69. Tell the person with communication difficulties after stroke about community-based communication and support groups (such as those provided by the voluntary sector) and encourage them to participate.

70. When persisting communication difficulties are identified at the person's 6-month or annual stroke reviews, refer them back to a speech and language therapist for detailed assessment, and offer treatment if there is potential for functional improvement.

71. Make sure that all written information (including that relating to medical conditions and treatment) is adapted for people with aphasia after stroke. This should include, for example, appointment letters, rehabilitation timetables and menus.

72. Help and enable people with communication difficulties after stroke to communicate their everyday needs and wishes, and support them to understand and participate in both everyday and major life decisions.

73. Ensure that environmental barriers to communication are minimised for people after stroke. For example, make sure signage is clear and background noise is minimised.

74. Refer people with suspected communication difficulties after stroke to a speech and language therapist for detailed analysis of speech and language impairments and assessment of their impact.

75. Speech and language therapists should:

- provide direct impairment-based therapy for communication impairments (for example, aphasia or dysarthria)
- help the person with stroke to use and enhance their remaining language and communication abilities
- teach other methods of communicating, such as gestures, writing and using communication props
- coach people around the person with stroke (including family members, carers and health and social care staff) to develop supportive communication skills to maximise the person's communication potential
- help the person with aphasia or dysarthria and their family or carer to adjust to a communication impairment

- support the person with communication difficulties to rebuild their identity
- support the person to access information that enables decision-making.

76. Offer training in communication skills (such as slowing down, not interrupting, using communication props, gestures, drawing) to the conversation partners of people with aphasia after stroke.

77. Provide physiotherapy for people who have weakness in their trunk or upper or lower limb, sensory disturbance or balance difficulties after stroke that have an effect on function.

78. People with movement difficulties after stroke should be treated by physiotherapists who have the relevant skills and training in the diagnosis, assessment and management of movement in people with stroke.

79. Treatment for people with movement difficulties after stroke should continue until the person is able to maintain or progress function either independently or with assistance from others (for example, rehabilitation assistants, family members, carers or fitness instructors).

80. Consider strength training for people with muscle weakness after stroke. This could include progressive strength building through increasing repetitions of body weight activities (for example, sit-to-stand repetitions), weights (for example, progressive resistance exercise), or resistance exercise on machines such as stationary cycles.

81. Encourage people to participate in physical activity after stroke.

82. Assess people who are able to walk and are medically stable after their stroke for cardiorespiratory and resistance training appropriate to their individual goals.

83. Cardiorespiratory and resistance training for people with stroke should be started by a physiotherapist with the aim that the person continues the programme independently based on the physiotherapist's instructions (see recommendation 84).

84. For people with stroke who are continuing an exercise programme independently, physiotherapists should supply any necessary information about interventions and adaptations so that where the person is using an exercise provider, the provider can ensure their programme is safe and tailored to their needs and goals. This information may take the form of written instructions, telephone conversations or a joint visit with the provider and the person with stroke, depending on the needs and abilities of the exercise provider and the person with stroke.

85. Tell people who are participating in fitness activities after stroke about common potential problems, such as shoulder pain, and advise them to seek advice from their GP or therapist if these occur.

86. Do not routinely offer wrist and hand splints to people with upper limb weakness after stroke.

87. Consider wrist and hand splints in people at risk after stroke (for example, people who have immobile hands due to weakness, and people with high tone), to:

- maintain joint range, soft tissue length and alignment
- increase soft tissue length and passive range of movement

- facilitate function (for example, a hand splint to assist grip or function)
- aid care or hygiene (for example, by enabling access to the palm)
- increase comfort (for example, using a sheepskin palm protector to keep fingernails away from the palm of the hand).

88. Where wrist and hand splints are used in people after stroke, they should be assessed and fitted by appropriately trained healthcare professionals and a review plan should be established.

89. Teach the person with stroke and their family or carer how to put the splint on and take it off, care for the splint and monitor for signs of redness and skin breakdown. Provide a point of contact for the person if concerned.

90. Do not routinely offer people with stroke electrical stimulation for their hand and arm.

91. Consider a trial of electrical stimulation in people who have evidence of muscle contraction after stroke but cannot move their arm against resistance.

92. If a trial of treatment is considered appropriate, ensure that electrical stimulation therapy is guided by a qualified rehabilitation professional.

93. The aim of electrical stimulation should be to improve strength while practising functional tasks in the context of a comprehensive stroke rehabilitation programme.

94. Continue electrical stimulation if progress towards clear functional goals has been demonstrated (for example, maintaining range of movement, or improving grasp and release).

95. Consider constraint-induced movement therapy for people with stroke who have movement of 20 degrees of wrist extension and 10 degrees of finger extension. Be aware of potential adverse events (such as falls, low mood and fatigue).

96. Provide information for people with stroke and their families and carers on how to prevent pain or trauma to the shoulder if they are at risk of developing shoulder pain (for example, if they have upper limb weakness and spasticity).

97. Manage shoulder pain after stroke using appropriate positioning and other treatments according to each person's need.

98. For guidance on managing neuropathic pain follow Neuropathic pain (NICE clinical guideline 96).

99. Offer people repetitive task training after stroke on a range of tasks for upper limb weakness (such as reaching, grasping, pointing, moving and manipulating objects in functional tasks) and lower limb weakness (such as sit-to-stand transfers, walking and using stairs).

100. Offer walking training to people after stroke who are able to walk, with or without assistance, to help them build endurance and move more quickly.

101. Consider treadmill training, with or without body weight support, as one option of walking training for people after stroke who are able to walk with or without assistance.

102. Offer electromechanical gait training to people after stroke only in the context of a research study.

103. Consider ankle–foot orthoses for people who have difficulty with swing-phase foot clearance after stroke (for example, tripping and falling) and/or stance-phase control (for example, knee and ankle collapse or knee hyper-extensions) that affects walking.

104. Assess the ability of the person with stroke to put on the ankle–foot orthosis or ensure they have the support needed to do so.

105. Assess the effectiveness of the ankle–foot orthosis for the person with stroke, in terms of comfort, speed and ease of walking.

106. Assessment for and treatment with ankle–foot orthoses should only be carried out as part of a stroke rehabilitation programme and performed by qualified professionals.

107. For guidance on functional electrical stimulation for the lower limb see Functional electrical stimulation for drop foot of central neurological origin (NICE interventional procedure guidance 278).

108. Provide occupational therapy for people after stroke who are likely to benefit, to address difficulties with personal activities of daily living. Therapy may consist of restorative or compensatory strategies.

- Restorative strategies may include:
- encouraging people with neglect to attend to the neglected side
- encouraging people with arm weakness to incorporate both arms
- establishing a dressing routine for people with difficulties such as poor concentration, neglect or dyspraxia which make dressing problematic.

- Compensatory strategies may include:
- teaching people to dress one-handed
- teaching people to use devices such as bathing and dressing aids.

109. People who have difficulties in activities of daily living after stroke should have regular monitoring and treatment by occupational therapists with core skills and training in the analysis and management of activities of daily living. Treatment should continue until the person is stable or able to progress independently.

110. Assess people after stroke for their equipment needs and whether their family or carers need training to use the equipment. This assessment should be carried out by an appropriately qualified professional. Equipment may include hoists, chair raisers and small aids such as long-handled sponges.

111. Ensure that appropriate equipment is provided and available for use by people after stroke when they are transferred from hospital, whatever the setting (including care homes).

112. Return-to-work issues should be identified as soon as possible after the person's stroke, reviewed regularly and managed actively. Active management should include:

- identifying the physical, cognitive, communication and psychological demands of the job (for example, multi-tasking by answering emails and telephone calls in a busy office)
- identifying any impairments on work performance (for example, physical limitations, anxiety, fatigue preventing attendance for a full day at

work, cognitive impairments preventing multi-tasking, and communication deficits)

- tailoring an intervention (for example, teaching strategies to support multi-tasking or memory difficulties, teaching the use of voice-activated software for people with difficulty typing, and delivery of work simulations)
- educating about the Equality Act 2010[e] and support available (for example, an access to work scheme)
- workplace visits and liaison with employers to establish reasonable accommodations, such as provision of equipment and graded return to work.

113. Manage return to work or long-term absence from work for people after stroke in line with recommendations in Managing long-term sickness and incapacity for work (NICE public health guidance 19).

114. Inform people after stroke that they can self-refer, usually with the support of a GP or named contact, if they need further stroke rehabilitation services.

115. Provide information so that people after stroke are able to recognise the development of complications of stroke, including frequent falls, spasticity, shoulder pain and incontinence.

116. Encourage people to focus on life after stroke and help them to achieve their goals. This may include:

- facilitating their participation in community activities, such as shopping, civic engagement, sports and leisure pursuits, visiting their place of worship and stroke support groups
- supporting their social roles, for example, work, education, volunteering, leisure, family and sexual relationships
- providing information about transport and driving (including DVLA requirements; see www.dft.gov.uk/dvla/medical/aag).

117. Manage incontinence after stroke in line with recommendations in Urinary incontinence in neurological disease (NICE clinical guideline 148) and Faecal incontinence (NICE clinical guideline 49).

118. Review the health and social care needs of people after stroke and the needs of their carers at 6 months and annually thereafter. These reviews should cover participation and community roles to ensure that people's goals are addressed.

119. For guidance on secondary prevention of stroke, follow recommendations in Lipid modification (NICE clinical guideline 67), Hypertension (NICE clinical guideline 127), Type 2 diabetes (NICE clinical guideline 87) and Atrial fibrillation (NICE clinical guideline 36).

120. Provide advice on prescribed medications in line with recommendations in Medicines adherence (NICE clinical guideline 76).

[e] HM Government (2010) Equality Act [online]

3.3 Key research recommendations

3.3.1 Upper limb electrical stimulation (ES)

What is the clinical and cost effectiveness of electrical stimulation (ES) as an adjunct to rehabilitation to improve hand and arm function in people after stroke, from early rehabilitation through to use in the community?

3.3.2 Intensive rehabilitation after stroke

In people after stroke what is the clinical and cost effectiveness of intensive rehabilitation (6 hours per day) versus moderate rehabilitation (2 hours per day) on activity, participation and quality of life outcomes?

3.3.3 Neuropsychological therapies

Which cognitive and which emotional interventions provide better outcomes for identified subgroups of people with stroke and their families and carers at different stages of the stroke pathway?

3.3.4 Shoulder pain

Which people with a weak arm after stroke are at risk of developing shoulder pain? What management strategies are effective in the prevention or management of shoulder pain of different aetiologies?

For further details please refer to Appendix L.

4 Methods

This chapter sets out in detail the methods used to generate the recommendations that are presented in subsequent chapters. This guidance was developed in accordance with the methods outlined in the NICE Guidelines Manual 2009 [187].

4.1 Developing the review questions and outcomes

Review questions were developed in a PICO framework (patient, intervention, comparison and outcome) for intervention reviews. This was to guide the literature searching process, appraisal, and synthesis of evidence and to facilitate the development of recommendations by the guideline development group (GDG). They were drafted by the NCGC technical team and refined and validated by the GDG. The questions were based on the key clinical areas identified in the scope (Appendix A).

A total of 22 review questions were identified.

Full literature searches, critical appraisals and evidence reviews were completed for all the specified clinical questions.

Chapter	**Review questions**	Outcomes
Structure and settings: stroke units	In people after stroke, does organised rehabilitation care (comprehensive, rehabilitation and mixed rehabilitation stroke units) improve outcome (mortality, dependency, requirement for institutional care and length of hospital stay)?	• Death • Death or dependency • Death or institutional care • Duration of stay in hospital or institution or both • Quality of life • Patient and carer satisfaction
Structure and settings: early supported discharge	In people after stroke what is the clinical and cost-effectiveness of early supported discharge versus usual care?	• Barthel Index • Length of hospital stay • Functional Independence Measure (FIM) • Caregiver strain index • Falls • Readmissions to hospital • Hospital Anxiety and Depression Scale (HADS) • Mortality • Quality Of Life • Nottingham Extended Activities of Daily Living
Service delivery: goal setting	Does the application of patient goal setting as part of planning stroke rehabilitation activities lead to an improvement in psychological wellbeing, functioning and activity?	• Psychological wellbeing • views about the quality of the goal setting process • satisfaction with outcome • health related quality of life • physical function • Activities of Daily Living (ADL)
Service delivery: intensity of	In people after stroke what is the clinical and cost-effectiveness of	• Length of stay • Functional Independence Measure (FIM)

Chapter	Review questions	Outcomes
rehabilitation	intensive rehabilitation versus standard rehabilitation?	• Barthel Index • Quality of Life (any measure) • Nottingham Activities of Daily Living • Rankin • Rivermead mobility index • Frenchay Activities Index
Support and information: supported information provision	What is the clinical and cost-effectiveness of supported information provision versus unsupported information provision on mood and depression in people with stroke?	• Impact on mood/depression: • Hospital Anxiety and Depression Scale (HADS) • General Health Questionnaire • Visual Analogue Mood Scale • Stroke Aphasic Depression Questionnaire (SAD-Q) • Geriatric Depression Scale • Beck Depression Inventory • Self-efficacy • General Self-efficacy Scale • Stroke Self-efficacy Questionnaire • Locus of Control Scale • Extended activities of daily living (EADL) • Nottingham extended ADL • Frenchay Activities Index • Yale mood question
Cognitive functions: visual neglect	In people after stroke what is the clinical and cost-effectiveness of cognitive rehabilitation versus usual care to improve spatial awareness and/or visual neglect?	• Mini-mental state examination (MMSE), • Behavioural Inattention Test (BIT), • Drawing tests (for example: clock drawing), • Line Bisection tests, • All cancellation tests (including: line cancellation, bell cancellation), • Sentence reading, • Target screen examinations (lump together all cancellation tests and drawing tests), • Rivermead Perceptual Assessment Battery (RPAB)
Cognitive functions: memory functions	In people after stroke what is the clinical and cost-effectiveness of memory strategies versus usual care to improve memory?	• Wechsler Memory Scale, • Rivermead behavioural memory assessment, • Mini-mental state examination (MMSE), • Addenbrook's Cognitive Examination-Revised, • Abbreviated Mental Test Score.
Cognitive functions: attention function	In people after stroke what is the clinical and cost-effectiveness of sustained attention training versus usual care to improve attention?	• Mini-mental state examination, Behavioural inattention test, drawing tests, line-bisection test, cancellation tests, sentence reading, target screen examinations, Rivermead Perceptual Assessment Battery
Emotional functioning	In people after stroke what is the clinical and cost effectiveness of psychological therapies provided to	• Quality of Life (for both carer and patient) – • Any QOL and depression outcomes

Chapter	Review questions	Outcomes
	the family (including the patients)?	including the following: stroke impact scale, EuroQoL, care giver burden scale, caregiver strain index, carer strain index, burden of stroke scale, Stroke and aphasia quality of life scale, ASCOT scale. • Occurrence of depression/anxiety/mood in carers – • Beck Depression Inventory, Beck Depression Inventory 2, Geriatric Depression Scale, neuropsychiatric inventory, Hospital Anxiety and Depression Scale (HADS),General health questionnaire, Visual Analogue Mood Scale, SADQ.
Vision: eye movement therapy	In people after stroke what is the clinical and cost-effectiveness of eye movement therapy for visual field loss versus usual care?	• Reading (speed and accuracy) • Eye movement tasks • Scanning • Letter Cancellation Test
Digestive systems: swallowing	In people after stroke what is the clinical and cost-effectiveness of interventions for swallowing versus alternative interventions	• Occurrence of aspiration pneumonia • Occurrence of chest infections • Reduction in hospital stay • Reduction in re-admission • Return to normal diet
Communication: Aphasia	In people after stroke is speech and language therapy compared to no speech and language therapy or placebo (social support and stimulation) effective in improving language/communication abilities and/or psychological wellbeing?	• Functional communication (language or communication skills sufficient to permit the transmission of message via spoken, written or non-verbal modalities, or a combination of these channels) • Formal measures of receptive language skills (language understanding) • Formal measures of expressive language skills (language production) • Overall level of severity of aphasia as measured by specialist test batteries (may include Western Aphasia Battery or Porch Index of Communicative Abilities) • Psychological or social wellbeing including depression, anxiety and distress • Patient satisfaction / carer and family views • Compliance / drop-out
Communication: Dysarthria	In people after stroke is speech and language therapy compared to social support and stimulation effective in improving dysarthria?	• Measures of functional communication • Formal measures of receptive language skills (language understanding) • Formal measures of expressive language skills (language production) • Psychological or social wellbeing including depression, anxiety and distress • Frenchay Dysarthria Assessment.

Chapter	Review questions	Outcomes
		• Measures of articulation (range, speed, strength, and co-ordination) • Perceptual measures of voice and prosody (for example, Vocal Profile Analysis) • Acoustic measures (for example, fundamental frequency, pitch perturbation (jitter), amplitude perturbation (shimmer), as measured by, computerised sound or spectrography)
Communication: intensity of speech and language therapy	In people after stroke with communication difficulties what is the clinical and cost-effectiveness of intensive speech therapy versus standard speech therapy?	• Any outcome reported in the papers. • Examples include: • Functional Assessment of Communication Skills for Adults (ASHA FACS) • Boston Naming Test • Western Aphasia Battery • Stroke Dysphasia Index • McKenna Graded Naming Test
Communication: Listener advice	What listener advice skills/information would help family members/carers improve communication in people with aphasia after stroke?	• Any outcome • Quality of life
Movement strength training	In people after stroke what is the clinical and cost-effectiveness of strength training versus usual care on improving function and reducing disability?	• Upper Limb • MRC Scale • Newton Metres • Fugl-meyer • Action Research Arm Test (ARAT) • Functional Independence Measurement (FIM) • Barthel Index • Adverse events –pain or spasticity • Lower Limb/Trunk • Timed Up and Go Test • Any timed walk • Walking distance • Functional; Independence Measure (FIM) • Barthel Index • Adverse events – falls, pain or spasticity
Movement: fitness training	In people after stroke, does cardiorespiratory or resistance fitness training improve outcome (fitness, function, quality of life, and mood) and reduce disability?	• Mortality rate • Dependence or level of disability • Physical fitness • Mobility • Physical function • Quality of life • Mood

Chapter	Review questions	Outcomes
Movement: hand and arm: orthoses upper limb	In people after stroke what is the clinical and cost-effectiveness of orthoses for prevention of loss of range of the upper limb versus usual care?	• Range of movement assessed by goniometry
Movement: hand and arm: electrical stimulation	In people after stroke what is the clinical and cost-effectiveness of Electrical Stimulation for hand function versus usual care?	• Any outcome reported in the paper. • Upper Limb outcomes including: ○ Action Research Arm Test (ARAT) ○ Fugl-Meyer Assessment (FMA) ○ 9 hole peg test ○ grip strength.
Movement: Hand and arm: constraint induced movement therapy	In people after stroke what is the clinical and cost-effectiveness of constraint-induced therapy versus usual care on improving function and reducing disability?	• Functional Independence Measure (FIM) • Barthel Index • Fugl-Meyer Assessment • Action Research Arm Test (ARAT) • Wolf Motor Function Test (WMFT) • 9 hole peg test • Any adverse event
Movement: Repetitive task training	In people after stroke what is the clinical and cost-effectiveness of repetitive task training versus usual care on improving function and reducing disability?	<u>Lower limb</u> • Any timed walk, 6m, 5m, 10m walk • Change in walking distance • Rivermead mobility index <u>Upper limb</u> Arm: • Fugl-Meyer Assessment, • Action Research Arm Test (ARAT) Hand: • Any peg hole test, • Frenchay Arm Test, • Motor Assessment Scale (MAS)
Movement: walking therapy: treadmill training	In people after stroke what is the clinical and cost-effectiveness of all treadmill versus usual care on improving walking? In people after stroke who can walk, what is the clinical and cost-effectiveness of treadmill plus body support versus treadmill only on improving walking?	• Walking speeds (5 m/ 10 m / 30 m) • Timed walk • Walking endurance • Functional Independence Measure (FIM) • Barthel Index • Rivermead Mobility Index
Movement: walking therapy: electromechanical	In people after stroke what is the clinical and cost-effectiveness of electromechanical gait training	• Walking speeds (5 metres/ 10 metres / 30 metres) • Any timed walk

Chapter	Review questions	Outcomes
gait training	versus usual care on improving function and reducing disability?	• Walking endurance • Functional Independence Measure (FIM) • Barthel Index • Rivermead Mobility Index
Movement: walking therapy: orthoses ankle-foot	In people after stroke what is the clinical and cost-effectiveness of ankle-foot orthoses of all types to improve walking function versus usual care?	• Gait speed: 6 min walk, 10 m timed walk • Lower limb MAS (stairs) • Timed walk • Walking endurance • Functional Independence Measure(FIM)/Barthel Index • Rivermead Mobility Index • Cadence • Gait symmetry (stance time, step length) • Quality of Life outcomes
Self-care	In people after stroke what is the clinical and cost-effectiveness of intensive occupational therapy focused specifically on personal activities of daily living versus usual care?	• Nottingham Extended Activities of Daily Living (NEADL) • Extended Activities of Daily Living (EADL) • Functional Independence Measure (FIM) • Barthel Index • Nottingham Stroke Dressing Assessment • Northwick Park Nursing Dependency Scale • Rivermead Mobility Index
Long term health and social support	In people after stroke what is the clinical and cost-effectiveness of interventions to aid return to work versus usual care?	• Same job same employer • Same job different employer • Different job same employer • Different job different employer • Unemployment • Retired due to ill health • Voluntary work • Benefit claims

During the development of questions concerning employment and return to work, provision of information, delivery of psychological therapies and early supported discharge, the GDG took the following issues into consideration:

- When the GDG formulated the question about aids to return to work, they acknowledged the universal consensus in the literature about the predictive factors restricting people after stroke to return to work. For this reason, they believed that the review of observational or cohort studies investigating this issue would not provide any added value in the formulation of recommendations for this guideline. The GDG believed that randomised trials investigating the impact of any type of intervention that could facilitate people to return to employment (either former or new employment) was a higher priority for the purposes of this guideline. In addition, the GDG noted that the nature of vocational interventions would be very diverse and tailored to individual circumstances (type of disability, nature of employment).

- During the formulation of a question related to provision of information for people after stroke and their carers, the GDG had a full discussion with regard to the large and heterogeneous area of information provision. We were clearly unable to address all information aspects within the timeline available. The GDG agreed that people after stroke live in a rich information environment, although it is not always tailored to the patient's needs. The GDG felt it was particularly important to look at the evidence pertaining to the provision of 'supported' information (information given with additional support of some kind such as the active provision of information, the encouragement of feedback, availability of peer support or use of interactive computer programme as opposed to the provision of leaflets/booklets in isolation) in order to investigate its impact on mood and depression in people after stroke and potentially direct the development of recommendations in this area.
- For the psychological support question, the GDG thought that this should investigate the effectiveness of the psychological therapies such as family therapy, cognitive-behaviour therapy and relationship counselling provided to the family (including the person with stroke) on the quality of life of people's with stroke and their carers. The group acknowledged that it was not usual to have a psychological therapy in isolation and therefore all of these therapies may also include some form of education in combination. In light of the publication of the 'Patient experience in adult NHS services' (NICE clinical guideline 138) the GDG agreed that this guidance could be cross-referenced where appropriate
- When formulating the question on early supported discharge, the GDG agreed to investigate the effectiveness of early supported discharge on improving specific patient and hospital related outcomes (such as mortality, quality of life, readmissions and length of stay in the hospital). The GDG did not consider that patients would have any different information needs after early supported discharge to other patients being discharged from hospital.

During the development of questions for this guideline scoping searches for cohort studies were undertaken and we consulted with the GDG on whether they were aware of any large cohort studies in these areas that would justify including studies other than randomised trials. None were identified.

4.2 Searching for evidence

4.2.1 Clinical literature search

The aim of the literature review was to identify all available, relevant published evidence in relation to the key clinical questions generated by the GDG. Systematic literature searches were undertaken to identify evidence within published literature in order to answer the review questions as per The Guidelines Manual [2009] [187]. Clinical databases were searched using relevant medical subject headings, free-text terms and study type filters where appropriate. Studies published in languages other than English were not reviewed. Where possible, searches were restricted to articles published in English language. All searches were conducted on core databases, MEDLINE, Embase, Cinahl and The Cochrane Library. Additional subject specific databases were used for some questions: PsycInfo for patient views, all searches were updated on 5th Oct 2012. No papers after this date were considered.

Search strategies were checked by looking at reference lists of relevant key papers, checking search strategies in other systematic reviews and asking the GDG for known studies in a specific area. The questions, the study types applied, the databases searched and the years covered can be found in Appendix [D].

During the scoping stage, a search was conducted for guidelines and reports on the websites listed below and on organisations relevant to the topic. Searching for grey literature or unpublished literature was not undertaken. All references sent by stakeholders were considered.

- Guidelines International Network database (www.g-i-n.net)
- National Guideline Clearing House (www.guideline.gov/)
- National Institute for Health and Clinical Excellence (NICE) (www.nice.org.uk)
- National Institutes of Health Consensus Development Program (consensus.nih.gov/)
- Health Information Resources, NHS Evidence (www.library.nhs.uk/)

The titles and abstracts of records retrieved by the searches were scanned for relevance to the GDG's clinical questions. Any potentially relevant publications were obtained in full text. These were assessed against the inclusion criteria and the reference lists were scanned for any articles not previously identified. Further references were also suggested by the GDG.

4.2.2 Health economic literature search

Systematic literature searches were also undertaken to identify health economic evidence within published literature relevant to the review questions. The evidence was identified by conducting a broad search relating to the guideline population in the NHS economic evaluation database (NHS EED), the Health Economic Evaluations Database (HEED) and health technology assessment (HTA) databases with no date restrictions. Additionally, the search was run on MEDLINE and Embase, with a specific economic filter, to ensure recent publications that had not yet been indexed by these databases were identified. Studies published in languages other than English were not reviewed. Where possible, searches were restricted to articles published in English language.

The search strategies for health economics are included in Appendix [D]. All searches were updated on 5th Oct 2012. No papers published after this date were considered.

4.3 Evidence of effectiveness

The Research Fellow:

- Identified potentially relevant studies for each review question from the relevant search results by reviewing titles and abstracts. Twenty per cent of the sift and selection of papers was quality assured by a second reviewer to eliminate any potential of selection bias or error. Full papers were then obtained.
- Reviewed full papers against pre-specified inclusion / exclusion criteria to identify studies that addressed the review question in the appropriate population and reported on outcomes of interest (review protocols are included in Appendix [D]).
- Critically appraised relevant studies using the appropriate checklist as specified in The Guidelines Manual[187]
- Extracted key information about the study's methods and results into evidence tables (evidence tables are included in Appendix [H]).
- Generated summaries of the evidence by outcome (included in the relevant chapter write-ups):
  - Randomised studies: meta-analysed, where appropriate and reported in GRADE profiles (for clinical studies) – see below for details.

4.3.1 Inclusion/exclusion criteria

The inclusion/exclusion of studies was based on the review protocols. The GDG were consulted about any uncertainty regarding inclusion/exclusion of selected studies. Minimum sample size and the proportion of participants with stroke were among the inclusion/exclusion criteria used for the selection of studies in the evidence reviews. The GDG agreed that (with the exception of review questions on cognitive functions and Functional Electrical Stimulation) the sample size of 20 participants (10 in each arm) would be the minimum requirement for a study to be included. For the review questions on cognitive functions, the minimum sample size would be set at 10 participants in

total due to the nature of interventions and the availability of studies in the literature. This decision on studies' sample size cut off points was made for pragmatic reasons.

We have included any study on stroke population at least 2 weeks post stroke. We didn't apply any restriction on selection of studies with populations on long term rehabilitation.

Due to the nature of interventions investigated in the following evidence reviews; memory strategies, eye movement therapy, swallowing, constraint induced movement therapy, treadmill, electromechanical gait training, ankle-foot, aids to return to work, which aimed ultimately to reduce disability and would be applicable to other populations (who have not experienced stroke), the GDG decided that we could use mixed populations for reviewing these questions, as long as the minimum proportion of participants with stroke in these studies was set at 50%. See the review protocols in Appendix E and excluded studies by the review questions (with their exclusion reasons) in Appendix M for full details.

4.3.2 Methods of combining clinical studies

Data synthesis for intervention reviews

Where possible, meta-analyses were conducted to combine the results of studies for each review question using Cochrane Review Manager (RevMan5) software. Fixed-effects (Mantel-Haenszel) techniques were used to calculate risk ratios (relative risk) for the binary outcomes. The outcome(s) was(were) analysed using an inverse variance method for pooling weighted mean differences and where the studies had different scales, standardised mean differences were used.

Statistical heterogeneity was assessed by considering the chi-squared test for significance at $p<0.1$ or an I-squared inconsistency statistic of >50% to indicate significant heterogeneity. Where significant heterogeneity was present, we carried out a sensitivity analysis with particular attention paid to allocation concealment, blinding and loss to follow-up (missing data). In cases where there was inadequate allocation concealment, unclear blinding or differential missing data more than 20% in the two groups, this was examined in a sensitivity analysis. For the latter, the duration of follow-up was also taken into consideration prior to including in a sensitivity analysis. No subgroup analyses were predefined with the exception of the clinical question for constraint induced therapy for which a subgroup analysis on duration of intervention (more or less than 5 hours) was pre-specified (see Appendix E for further details).

If no sensitivity analysis was found to completely resolve statistical heterogeneity then a random effects (DerSimonian and Laird) model was employed to provide a more conservative estimate of the effect.

For continuous outcomes, the means and standard deviations were required for meta-analysis. However, in cases where standard deviations were not reported, the standard error was calculated if the p-values or 95% confidence intervals were reported and meta-analysis was undertaken with the mean and standard error using the generic inverse variance method in Cochrane Review Manager (RevMan5) software. When the only evidence was based on studies summarised results by only presenting medians (and interquartile range), or only p values this information was included in the GRADE tables without calculating the relative and absolute effect. Consequently, imprecision of effect could not be assessed when results were not presented in the studies by means and standard deviations.

For binary outcomes, absolute event rates were also calculated using the GRADEpro software using event rate in the control arm of the pooled results.

The results from cross over studies were combined in a meta-analysis with those from parallel randomised trials, only after corrections have been made to the standard error for the crossover trials.

4.3.3 Type of studies

Systematic reviews, double blinded, single blinded and unblinded parallel randomised controlled trials (RCTs) and cross over randomized studies were included in the evidence reviews for this guideline.

We included randomised trials, as they are considered the most robust type of study design that could produce an unbiased estimate of the intervention effects. The GDG believed that the reason why no large trials were found for this population was largely because stroke units are relatively new and prior to their formation it has not been possible to conduct large multi-centre RCTs.

We also searched for systematic reviews of cohort studies, however none was found in any review question. The GDG decided not to include individual cohort studies. Cohort studies have been based in rehabilitation units where there are mixed population groups and extracting stroke data from those mixed populations would be challenging. Preliminary searches undertaken did not find any large cohort studies; therefore the GDG agreed that individual cohort studies would not provide any added value to the reviews of individual interventions.

For most of the reviews the content of interventions and the referred populations within the included studies was found to be very diverse, making the extraction of relevant data challenging and time consuming. In addition, the GDG had difficulties in drawing overall conclusions on the body of evidence presented and it was often not possible to make recommendations specifying what interventions should comprise of. In these instances, the GDG decided that the results of each outcome should be presented separately for each study and a meta-analysis could not be conducted. Due to the diversity of interventions, it was decided to include a summary table of studies included with individual characteristics (population, intervention, control, outcomes) at the beginning of each evidence review.

4.3.4 Type of analysis

Estimates of effect from individual studies were based on Intention To Treat (ITT) analysis with the exception of the outcome of experience of adverse events whereas we used Available Case Analysis (ACA). ITT analysis is where all participants included in the randomisation process were considered in the final analysis based on the intervention and control groups to which they were originally assigned. We assumed that participants in the trials lost to follow-up did not experience the outcome of interest (for categorical outcomes) and they would not considerably change the average scores of their assigned groups (for continuous outcomes).

It is important to note that ITT analyses tend to bias the results towards no difference. ITT analysis is a conservative approach to analyse the data, and therefore the effect may be smaller than in reality.

However, the majority of outcomes selected to be reviewed were continuous outcomes, very few people dropped out and most of the studies reported data on an ITT basis.

4.3.5 Appraising the quality of evidence by outcomes

The evidence for outcomes from the included RCTs was evaluated and presented using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group (http://www.gradeworkinggroup.org/). The software (GRADEpro) developed by the GRADE working group was used to assess the quality of each outcome, taking into account individual study quality and the meta-analysis results. The summary of

studies characteristics and findings was presented in one table in this guideline. The "Clinical/Economic Study Characteristics" table includes details of the quality assessment while the "Clinical /Economic Summary of Findings" table includes pooled outcome data and where appropriate, an absolute measure of intervention effect and the summary of quality of evidence for that outcome. In this table, the columns for intervention and control indicate summaries of the sum of the sample size for continuous outcomes. For binary outcomes such as number of patients with an adverse event, the event rates (n/N: number of patients with events divided by sum of number of patients) are shown with percentages. Reporting or publication bias was only taken into consideration in the quality assessment and included in the Clinical Study Characteristics table if it was apparent.

Each outcome was examined separately for the quality elements listed and defined in **Table 1** and each graded using the quality levels listed in **Table 2**. The main criteria considered in the rating of these elements are discussed below (see section 4.3.6 Grading of Evidence). Footnotes were used to describe reasons for grading a quality element as having serious or very serious problems. The ratings for each component were summed to obtain an overall assessment for each outcome.

Table 3: The GRADE toolbox is currently designed only for randomised trials and observational studies

Table 1: Descriptions of quality elements in GRADE for intervention studies

Table 1: Description of quality elements in GRADE for intervention studies

Quality element	Description
Limitations	Limitations in the study design and implementation may bias the estimates of the treatment effect. Major limitations in studies decrease the confidence in the estimate of the effect.
Inconsistency	Inconsistency refers to an unexplained heterogeneity of results.
Indirectness	Indirectness refers to differences in study population, intervention, comparator and outcomes between the available evidence and the review question, or recommendation made.
Imprecision	Results are imprecise when studies include relatively few patients and few events and thus have wide confidence intervals around the estimate of the effect relative to the clinically important threshold.
Publication bias	Publication bias is a systematic underestimate or an overestimate of the underlying beneficial or harmful effect due to the selective publication of studies.

Table 2: Levels of quality elements in GRADE

Level	Description
None	There are no serious issues with the evidence
Serious	The issues are serious enough to downgrade the outcome evidence by one level
Very serious	The issues are serious enough to downgrade the outcome evidence by two levels

Table 3: Overall quality of outcome evidence in GRADE

Level	Description
High	Further research is very unlikely to change our confidence in the estimate of effect
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate

Level	Description
Very low	Any estimate of effect is very uncertain

4.3.6 Grading the quality of clinical evidence

After results were pooled, the overall quality of evidence for each outcome was considered. The following procedure was adopted when using GRADE:

11. A quality rating was assigned, based on the study design. RCTs start HIGH and observational studies as LOW, uncontrolled case series as LOW or VERY LOW.
12. The rating was then downgraded for the specified criteria: Study limitations, inconsistency, indirectness, imprecision and reporting bias. These criteria are detailed below. Observational studies were upgraded if there was a large magnitude of effect, dose-response gradient, and if all plausible confounding would reduce a demonstrated effect or suggest a spurious effect when results showed no effect. Each quality element considered to have 'serious' or 'very serious' risk of bias was rated down 1 or 2 points respectively.
13. The downgraded/upgraded marks were then summed and the overall quality rating was revised. For example, all RCTs started as HIGH and the overall quality became MODERATE, LOW or VERY LOW if 1, 2 or 3 points were deducted respectively.
14. The reasons or criteria used for downgrading were specified in the footnotes.

The details of criteria used for each of the main quality element are discussed further in the following sections 4.3.7 to 4.3.10.

4.3.7 Study limitations

The main limitations for randomised controlled trials are listed in **Table 4**.

Outcomes from studies which were not double blinded were downgraded on study limitations due to the higher risk of bias. However, the GDG expressed their concern that conducting double blinded trials in stroke rehabilitation was not practical as it would be impossible to blind the trial participant due to the nature of the interventions delivered in stroke rehabilitation. However, single blinded and unblinded trials were downgraded to maintain a consistent approach in quality rating across the guideline following the application of GRADE system, recognising that a double blinded trial would provide the least biased outcomes in a clinical setting. **Table 4** listed the limitations considered for randomised controlled trials.

Table 4: Study limitations of randomised controlled trials

Limitation	Explanation
Allocation concealment	Those enrolling patients are aware of the group to which the next enrolled patient will be allocated (major problem in "pseudo" or "quasi" randomised trials with allocation by day of week, birth date, chart number, etc.)
Lack of blinding	Patient, caregivers, those recording outcomes, those adjudicating outcomes, or data analysts are aware of the arm to which patients are allocated. Baseline differences are also assessed in this category.
Incomplete accounting of patients and outcome events	Loss to follow-up not accounted and failure to adhere to the intention to treat principle when indicated
Selective outcome reporting	Reporting of some outcomes and not others on the basis of the results
Other limitations	For example:

Limitation	Explanation
	• Stopping early for benefit observed in randomised trials, in particular in the absence of adequate stopping rules • Use of invalidated patient-reported outcomes • Carry-over effects in cross-over trials • Recruitment bias in randomised trials

4.3.8 Inconsistency

Inconsistency refers to an unexplained heterogeneity of results. When estimates of the treatment effect across studies differ widely (i.e. heterogeneity or variability in results), this suggests true differences in underlying treatment effect. When heterogeneity exists (Chi square p<0.1 or I- squared inconsistency statistic of >50%), but no plausible explanation can be found (for example acute or chronic stroke populations, duration of intervention, different follow-up periods), the quality of evidence was downgraded by one or two levels, depending on the extent of uncertainty to the results contributed by the inconsistency in the results. Due to the diversity of interventions used in the included trials for this guideline, there were cases where the GDG believed the presentation of evidence should be kept separate and explanatory footnotes were given in GRADE tables where appropriate. In addition to the I- square and Chi square values, the decision for downgrading was also dependent on factors such as whether the intervention is associated with benefit in all other outcomes or whether the uncertainty about the magnitude of benefit (or harm) of the outcome showing heterogeneity would influence the overall judgment about net benefit or harm (across all outcomes).

If inconsistency could be explained based on pre-specified subgroup analysis, the GDG took this into account and considered whether to make separate recommendations based on the identified explanatory factors, i.e. population and intervention. Where subgroup analysis gives a plausible explanation of heterogeneity, the quality of evidence would not be downgraded. The most common factor of subgroup analysis was the time since stroke event and the GDG considered the evidence of some outcomes separately for acute and chronic stroke patients.

4.3.9 Indirectness

Directness refers to the extent to which the populations, intervention, comparisons and outcome measures are similar to those defined in the inclusion criteria for the reviews. Indirectness is important when these differences are expected to contribute to a difference in effect size, or may affect the balance of harms and benefits considered for an intervention. The GDG decided that for specific questions (for example the review of interventions to assess clinical and cost effectiveness of interventions to aid return to work) the review of evidence could include mixed populations with at least 50% stroke patients.

4.3.10 Imprecision

The sample size, event rates, the resulting width of confidence intervals and the minimal important difference in the outcome between the two groups were the main criteria considered.

The thresholds of important benefits or harms, or the MID (minimal important difference) for an outcome are important considerations for determining whether there is a “clinically important” difference between intervention and control groups and in assessing imprecision. For continuous outcomes, the MID is defined as “the smallest difference in score in the outcome of interest that informed patients or informed proxies perceive as important, ether beneficial or harmful, and that would lead the patient or clinician to consider a change in the management ([98 124,231,232]). An effect

estimate larger than the MID is considered to be "clinically important". For dichotomous outcomes, the MID is considered in terms of changes of absolute risk.

The difference between two interventions, as observed in the studies, was compared against the MID when considering whether the findings were of "clinical importance"; this is useful to guide decisions. For example, if the effect was small (less than the MID), this finding suggests that there may not be enough difference to strongly recommend one intervention over the other based on that outcome.

We searched the literature for published studies which gave a minimal important difference point estimate for the outcomes specified in the protocol and agreement was obtained from the GDG for their use in assessing imprecision throughout the reviews in the guideline. Table 5 presents the MID thresholds used for the specified outcomes and the source of base evidence. Where no published studies were found on MIDs for outcomes, the default GRADE pro MIDs was used. For categorical data, we checked whether the confidence interval of the effect crossed one or two ends of the range of 0.75-1.25. For quantitative outcomes two approaches were used. When only one trial was included as the evidence base for an outcome, the mean difference was converted to the standardized mean difference (SMD) and checked to see if the confidence interval crossed 0.5. However, the mean difference (95% confidence interval) was still presented in the Grade tables. If two or more included trials reported a quantitative outcome then the default approach of multiplying 0.5 by standard deviation (taken as the median of the standard deviations across the meta-analysed studies) was employed. When the default MIDs were used, the GDG would assess the estimate of effect with respects to the MID, and then the imprecision may be reconsidered.

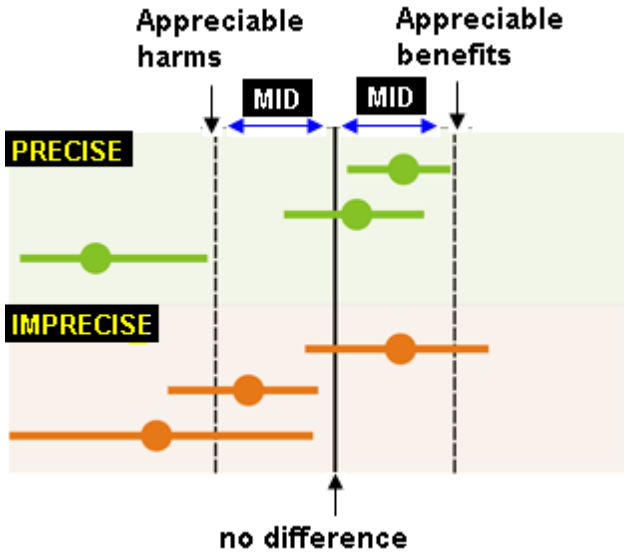
The confidence interval for the pooled or best estimate of effect was considered in relation to the MID, as illustrated in Figure 1. Essentially, if the confidence interval crossed the MID threshold, there was uncertainty in the effect estimate in supporting our recommendation (because the CI was consistent with two decisions) and the effect estimate was rated as imprecise.

Table 5: Agreed MIDs from the literature

Outcomes	Agreed MID	Evidence base	Other considerations
Barthel Index	1.85 points (SE 1.45)	Hsieh, Wang, Wu, Chen, Sheu, Hsieh 2007. [116]	• Taiwan setting (n=43) • Paper's aim to estimate MID
Action Research Arm Test (ARAT)	12 and 17 points for the affected dominant and non-dominant sides respectively	Lang, Edwards, Birkenmeier, Dromerick 2008.[141]	• Inpatient rehabilitation hospital setting- early after stroke patients with hemiparesis (N=52) • Paper's aim to estimate MID.
Fugl-Meyer Assessment (FMA)	Difference by 10% of the total scale	Van der Lee, Beckerman, Lankhorst and Bouter 2001. [269]	Paper assessed sensitivity of the research arm test in 22 chronic stroke patients
Wolf Motor Function Test (WMFT)	An improvement of 19 seconds on the affected dominant side (16% of the 120 second limit)	Lang, Edwards, Birkenmeier, Dromerick 2008[141]	• Inpatient rehabilitation hospital setting- early after stroke patients with hemiparesis (N=52) • Paper's aim to estimate MID.
Motor Activity Log (MAL)	At least 1.0 and 1.1 points (17-18% of the scale)for the affected dominant and non-	Lang, Edwards, Birkenmeier, Dromerick 2008[141]	• Inpatient rehabilitation hospital setting- early after stroke patients with hemiparesis (N=52)

Outcomes	Agreed MID	Evidence base	Other considerations
	dominant sides respectively		• Paper's aim to estimate MID.
Functional Independence Measure (FIM)	22 points for the total FIM, 17 points (on the 105 point scale- 16%) for the motor FIM and 3 points for the cognitive FIM.	Beninato, Gill-Body, Salles, Stark, Black-Schaffer, Stein. 2006. [24]	• Patients with stroke in long term acute hospital. (N=113) • Paper's aim to estimate MID
Walking speed (for chronic stroke patients)	20 cm/sec	Perry J, Garrett M, Gronley JK, Mulroy SJ. Classification of walking handicap in stroke population. *Stroke 1995;* 26: 982-89. [202]	chronic stroke patients (over 3 months post stroke)
Walking speed (for acute stroke patients)	16 cm/sec	Tilson J K, Sullivan K, Cen S Y, Rose D.K, C H. Koradia, S P. Azen, P W. Duncan 2010.[258]	• First time stroke patients (20-60 days post stroke) with severe gait impairments (N=283) • Paper's aim to estimate MID for gait speed
Timed Up and Go	10 sec	Perry J, Garrett M, Gronley JK, Mulroy SJ. Classification of walking handicap in stroke population. *Stroke 1995;* 26: 982-89. [202]	
Stairs Test	15 sec	Podsiadlo D, Richardson S. The timed 'Up & Go': a test of basic functional mobility for frail elderly persons. *J Am Geriatr Soc 1991;* 39: 142-48.[207]	
6 minute walk test	28 m	Dean CM, Richards C L, Malouin F 2000.[58]	
Range of movement (wrist extensibility)	5° change (SD 4.1 °)	Lannin N A, Cusick A, McCluskey A, Herbert R D 2007.[144]	MID taken from sample size calculation (N=63)

Figure 1: Illustration of precise and imprecision outcomes based on the confidence interval of outcomes in a Forrest plot



Source: Figure adapted from GRADEPro software.

MID = minimal important difference determined for each outcome. The MIDs are the threshold for appreciable benefits and harms. The confidence intervals of the top three points of the diagram were considered precise because the upper and lower limits did not cross the MID. Conversely, the bottom three points of the diagram were considered imprecise because all of them crossed the MID and reduced our certainty of the results.

4.4 Evidence of cost-effectiveness

The Guideline Development Group (GDG) is required to make decisions based on the best available evidence of both clinical and cost effectiveness. Guideline recommendations should be based on the estimated costs of the treatment options in relation to their expected health benefits (that is, their 'cost effectiveness'), rather than on the total cost or resource impact of implementing them. Thus, if the evidence suggests that an intervention provides significant health benefits at an acceptable cost per patient treated, it should be recommended even if it would be expensive to implement across the whole population.

Evidence on cost effectiveness related to the key clinical issues being addressed in the guideline was sought. The health economist undertook:

- A systematic review of the published economic literature.
- New cost-effectiveness analysis in priority areas.

When no relevant published studies were found, and a new analysis was not prioritised, the GDG made a qualitative judgement about cost effectiveness by considering expected differences in resource use between comparators and relevant UK NHS unit costs alongside the results of the clinical review of effectiveness evidence. Where considered useful, this included calculation of expected cost differences and consideration of the QALY gain that would be required to justify the expected additional cost of the intervention being considered. Unit costs were based on published national source where available. Staff costs are reported using the typical salary band of someone delivering the intervention as identified by clinical GDG members. It should be noted however that in

practice staff bands will vary due to the need for a skill mix across teams. Inputs to calculations should not be interpreted as recommendations about who should deliver care.

4.4.1 Literature review

The health economist:

- Identified potentially relevant studies for each review question from the economic search results by reviewing titles and abstracts – full papers were then obtained.
- Reviewed full papers against pre-specified inclusion / exclusion criteria to identify relevant studies (see below for details).
- Critically appraised relevant studies using the economic evaluations checklist as specified in The Guidelines Manual[187].
- Extracted key information about the study's methods and results into evidence tables (evidence tables are included in Appendix H).
- Generated summaries of the evidence in NICE economic evidence profiles (included in the relevant chapter write-ups) – see below for details.

4.4.1.1 Inclusion/exclusion

Full economic evaluations (studies comparing costs and health consequences of alternative courses of action: cost–utility, cost-effectiveness, cost-benefit and cost-consequence analyses) and comparative costing studies that addressed the review question in the relevant population were considered potentially applicable as economic evidence.

Studies that only reported cost per hospital (not per patient), or only reported average cost effectiveness, without disaggregated costs and effects, were excluded. Abstracts, posters, reviews, letters/editorials, foreign language publications and unpublished studies were excluded. Studies judged to have an applicability rating of 'not applicable' were excluded (this included studies that took the perspective of a non-OECD country).

Remaining studies were prioritised for inclusion based on their relative applicability to the development of this guideline and the study limitations. For example, if a high quality, directly applicable UK analysis was available other less relevant studies may not have been included. Where exclusions occurred on this basis, this is noted in the relevant section.

For more details about the assessment of applicability and methodological quality see the economic evaluation checklist (The Guidelines Manual, Appendix H[187]) and the health economics research protocol in Appendix E.

4.4.1.2 NICE economic evidence profiles

The NICE economic evidence profile has been used to summarise cost and cost-effectiveness estimates. The economic evidence profile shows, for each economic study, an assessment of applicability and methodological quality, with footnotes indicating the reasons for the assessment. These assessments were made by the health economist using the economic evaluation checklist from The Guidelines Manual, Appendix H[187]. It also shows incremental costs, incremental effects (for example, QALYs) and the incremental cost-effectiveness ratio from the primary analysis, as well as information about the assessment of uncertainty in the analysis. See **Table 6** for more details.

If a non-UK study was included in the profile, the results were converted into pounds sterling using the appropriate purchasing power parity[194].

Table 6: Content of NICE economic profile

Item	Description
Study	First author name, reference, date of study publication and country perspective.
Limitations	An assessment of methodological quality of the study(a): Minor limitations – the study meets all quality criteria, or the study fails to meet one or more quality criteria, but this is unlikely to change the conclusions about cost effectiveness. Potentially serious limitations – the study fails to meet one or more quality criteria, and this could change the conclusion about cost effectiveness Very serious limitations – the study fails to meet one or more quality criteria and this is very likely to change the conclusions about cost effectiveness. Studies with very serious limitations would usually be excluded from the economic profile table.
Applicability	An assessment of applicability of the study to the clinical guideline, the current NHS situation and NICE decision-making(a): Directly applicable – the applicability criteria are met, or one or more criteria are not met but this is not likely to change the conclusions about cost effectiveness. Partially applicable – one or more of the applicability criteria are not met, and this might possibly change the conclusions about cost effectiveness. Not applicable – one or more of the applicability criteria are not met, and this is likely to change the conclusions about cost effectiveness.
Other comments	Particular issues that should be considered when interpreting the study.
Incremental cost	The mean cost associated with one strategy minus the mean cost of a comparator strategy.
Incremental effects	The mean QALYs (or other selected measure of health outcome) associated with one strategy minus the mean QALYs of a comparator strategy.
ICER	Incremental cost-effectiveness ratio: the incremental cost divided by the respective QALYs gained.
Uncertainty	A summary of the extent of uncertainty about the ICER reflecting the results of deterministic or probabilistic sensitivity analyses, or stochastic analyses of trial data, as appropriate.

(a) Limitations and applicability were assessed using the economic evaluation checklist from The Guidelines Manual, Appendix H[187]

4.4.2 Undertaking new health economic analysis

As well as reviewing the published economic literature for each review question, as described above, new economic analysis was undertaken by the health economist in selected areas. Priority areas for new health economic analysis were agreed by the GDG after formation of the review questions and consideration of the available health economic evidence.

The GDG identified intensity of rehabilitation as the highest priority area for an original economic model. This issue impacts the largest group of people in the guideline as it relates to the whole population rather than a specific subset. In addition, the GDG considered that the intensity of rehabilitation provided currently varies considerably from service to service in terms of hours per day and duration of therapy, and it is generally lower than that currently recommended in the NICE quality standard for ongoing rehabilitation. Therefore recommendations in this area were considered likely to have the biggest impact on NHS resources and patient outcomes.

The following general principles were adhered to in developing the cost-effectiveness analysis:

- Methods were consistent with the NICE reference case[185].
- The GDG was consulted during the construction and interpretation of the model.

- Model inputs were based on the systematic review of the clinical literature supplemented with other published data sources where possible.
- When published data was not available expert opinion was used to populate the model.
- Model inputs and assumptions were reported fully and transparently.
- The results were subject to sensitivity analysis and limitations were discussed.
- The model was peer-reviewed by another health economist at the NCGC.

Full methods for the intensity of rehabilitation cost effectiveness analysis are described in Appendix K.

4.4.3 Cost-effectiveness criteria

NICE's report 'Social value judgements: principles for the development of NICE guidance' sets out the principles that GDGs should consider when judging whether an intervention offers good value for money[186,187].

In general, an intervention was considered to be cost effective if either of the following criteria applied (given that the estimate was considered plausible):

a. The intervention dominated other relevant strategies (that is, it was both less costly in terms of resource use and more clinically effective compared with all the other relevant alternative strategies), or
b. The intervention cost less than £20,000 per quality-adjusted life-year (QALY) gained compared with the next best strategy.

If the GDG recommended an intervention that was estimated to cost more than £20,000 per QALY gained, or did not recommend one that was estimated to cost less than £20,000 per QALY gained, the reasons for this decision are discussed explicitly in the 'from evidence to recommendations' section of the relevant chapter with reference to issues regarding the plausibility of the estimate or to the factors set out in the 'Social value judgements: principles for the development of NICE guidance'[186].

If a study reported the cost per life year gained but not QALYs, the cost per QALY gained was estimated by multiplying by an appropriate utility estimate to aid interpretation. The estimated cost per QALY gained is reported in the economic evidence profile with a footnote detailing the life-years gained and the utility value used. When QALYs or life years gained are not used in the analysis, results are difficult to interpret unless one strategy dominates the others with respect to every relevant health outcome and cost.

4.5 Post consultation protocol including modified Delphi methodology

During consultation, substantial stakeholder comments were received which highlighted a number of significant issues in relation to the guideline scope and recommendations developed in the guideline. Stakeholders raised concerns that the guideline was incomplete because of the number of areas in the rehabilitation patient care pathway that the guideline had not covered, and this may result in therapies and services for the stroke population being reduced or even withdrawn. The areas identified in the consultation period included:

- service delivery, roles and responsibility of the multidisciplinary team/stroke rehabilitation services
- holistic assessment, care planning, goal setting, ongoing review and monitoring
- transfer of care/discharge planning and interface with social care
- long-term health and social support for people after stroke and patient information needs

Stakeholders also considered that some topics included in the scope had not been addressed adequately, including mood disorders (depression and anxiety), physical fitness and exercise, other speech and language therapies and diplopia.

The focus of the outcomes for the interventions included in the guideline has been on function and mobility as these were considered by the Guideline Development Group (GDG) to have the biggest impact on patients' lives. However many stakeholders considered that the patient experience and holistic approaches to care had been neglected and represented a major gap in the guidance. In light of the comments received from stakeholders, the GDG agreed that additional work should be carried out for some of these areas or reference made to other NICE guidance, in order to produce a more complete piece of guidance that would be useful to health professionals delivering rehabilitation to a stroke population. The current guidance has followed standard NICE methodology and the GDG were in agreement that for those areas where either weak or no evidence was available a robust process needed to be followed.

In consultation with NICE and the GDG the NCGC technical team conducted additional work to address the areas identified by stakeholders and not covered in the original scope. Comprehensive searches of databases with terms designed to identify evidence related to the topics outlined above were undertaken following the NICE process but restricted to retrieve other guidelines and systematic reviews only. In addition a similar scoping search was done for economic evidence relating to the same areas. The search strategy was limited to capture only economic evaluations. A first sift was undertaken to identify potentially relevant economic papers related to the topics listed above.

Reviews of the clinical and economic literature were undertaken following the usual NICE process and presented to the GDG who used this evidence as a basis to make further recommendations.

Where there were recommendations in other NICE guidance relevant to the stroke population and addressed comments highlighted by stakeholders, cross reference to these was made rather than undertaking further original work.

Relevant guidelines identified from the comprehensive search were quality assessed using the AGREE II tool checklist. Those of sufficient quality were reviewed for recommendations relating to the topics identified in the stakeholder consultation.

The full protocol can be found in Appendix B.

Modified Delphi consensus methodology

As the evidence base was weak or absent for many of the areas stakeholders wished the guideline to include a different methodology. This was seen as necessary since it would provide a robust process to enable the GDG to make further recommendations. Where there was a lack of published evidence the NCGC technical team used a modified Delphi method (anonymous, multi-round, consensus-building technique) based on other available guidelines or expert opinion. This type of survey has been used successfully for generating, analysing and synthesising expert view to reach a group consensus position. The technique uses sequential questionnaires to solicit individual responses, with the potential threat of peer pressure removed[95]. This is an important consideration and is a key strength of the technique. Strauss and Ziegler's[249] (1975) seminal work on the technique highlights the features of the technique:

- Enables the effective use of a panel of experts
- Data is generated through sequential questioning
- Highlights consensus and divergent opinion
- Anonymity is guaranteed
- It handles judgemental data effectively

In NICE processes, little or no evidence for reviews is an exceptional circumstance when formal consensus techniques (such as the Delphi method) can be adopted[187]. The methods and process proposed was discussed with methodological advisers within NICE and the protocol was agreed and signed off by them prior to work being carried out.

Delphi statements were distilled from the content of existing national and international stroke rehabilitation guidelines. The identified guidelines were quality assured by two research fellows using the Appraisal of Guidelines for Research and Evaluation (AGREE-II) instrument as described in the Appendix F The relevant sections of the guidelines were summarised (and noted whether the recommendations were based on consensus or evidence) and these summaries were used as the basis for draft statements. Statements were then discussed and revised with two external experts recruited to act as consultants in the development of the survey statements. A table with the relevant guideline sections and first draft statement can be found in Appendix F.

The Delphi panel comprised of stroke rehabilitation clinicians and other professionals with significant experience in stroke rehabilitation (referred to as the Delphi panel) covering a wide range of disciplines involved in stroke care. Members of the panel were identified by means of nomination by the GDG, and these were then collated and reviewed by the chair of the GDG and the RCP Intercollegiate Stroke Working Party and, after removal of duplicates, inspected for representativeness. In the first instance 164 experts were contacted and invited to participate. The professions comprised of :geriatricians, neurologists, nurses, occupational therapists, people from patient representation/organisations, physiotherapists, psychologists, research / policy makers, social workers, speech and language therapists, stroke physicians and other' health care professionals (for example orthoptists, dieticians, GPs and pharmacists).

A survey, consisting of 68 statements plus 3 demographic questions (profession, setting, and geographic area), was then circulated to the Delphi panel. Free text boxes were available for panel comments, these were then evaluated and used to revise and refine statements if necessary. This process was carried out in conjunction with the consultant experts as well as the Chair of the guideline. The results from each round was summarised and then communicated to participants. Four rounds of the survey were undertaken in total. For the majority of statements (plus demographics), a Likert scale was applied to indicate the level of agreement. Some statements employed multiple choice options. A four option Likert scale was used: strongly disagree, disagree, agree and strongly agree. The purpose of using a four point scale was to be consistent for Delphi panel members who may have been familiar with both the size of scale and terms used to support Delphi processes from previous consensus work in Stroke Care. In published literature about Delphi methodology there has been much debate about what percentage of agreement among Delphi panel members constitutes consensus (see Murphy et al's 1998 Health Technology Assessment)[181] on this subject). While there is no universal agreement or guidelines on the level of consensus, Keeney et al. (2011)[135] suggested that researchers should decide on the consensus level before commencing the study and consider using a high level of consensus, such as 70%.

In line with Keeney et al (2011)[135] a level of 70% or higher of participants 'strongly agreeing' was set for rounds 1 and 2, with this threshold for consensus being reviewed in rounds 3 and 4. In analysing the data, and in understanding the difficulty of reaching consensus in the latter rounds where iteration had featured, a decision was reached by the technical team to lower the threshold marginally to 67% 'strongly agree' as long as the majority of other participant responses were 'agree'. The analysis of this in every item adopting this approach in the latter rounds was that the combined Delphi panel response was in excess of 90% of participants either responding 'strongly agree' (at least 67% of total participant response) or 'agree'. This was a pragmatic response by the technical team and meets published criteria that consensus is achieved when 66.6% of a Delphi panel agrees. Statements that reached these levels would not feature in the next round. Statements that did not reach this level were reviewed by the technical team with the GDG chair and expert consultants and were amended based on the panel's comments in the survey. When there were low

levels of disagreement, some statements were not edited and re-included in the next round. With already low levels of disagreement it was felt that re-inclusion of these statements would encourage panel members who 'agreed' to shift to a 'strongly agree' response. This procedure of re-evaluation continued until either the consensus rate was achieved or until the Delphi panel members no longer modified their previous estimates / responses (or comments). In summary, when both the level of agreement and the type of comments no longer changed it was agreed that a further round would not achieve consensus. The comments that illustrated these differences in opinions or comments that showed agreement but no longer changed were then highlighted in the final Delphi report.

There is no complete agreement about when to terminate a Delphi survey, and one researcher has stated 'if no consensus emerges, at least a crystallizing of the disparate positions usually becomes apparent' (Gordon, 1971)[97].

Since there was an over-representation of physiotherapists in the Delphi panel responses were inspected by profession in the analysis. There were no systematic differences in physiotherapists' responses compared to those of other professions. Hence further details of responses per profession were not included in the report. However, in the GDG meeting in which recommendations were drafted from the Delphi statements GDG members were informed about the Delphi composition and asked to consider this in their discussion of the statements.

The full report was circulated to the GDG. The consensus statements emerging from the iterative modified Delphi technique were presented to the GDG and formed the basis of discussion. The economic search results were rechecked to see if there were any economic analyses relating to areas where new recommendations had been made. Since no economic evaluations was found on the new areas of the guideline, the GDG made a qualitative judgement about the cost effectiveness of the interventions they wanted to recommend based on the Delphi statements. Economic considerations were drafted for all those new recommendations where economic implications were deemed important.

A summary of the areas that are addressed in the post consultation process and the type of evidence identified is provided in Table 7 below.

Table 7: Summary of post-consultation topics and level of evidence identified (consensus refers to those areas that will be covered by the modified Delphi.

Areas to address	Evidence
service delivery multidisciplinary teams stroke units	 consensus systematic review identified
assessment for rehab care plans goal setting ongoing monitoring	consensus consensus systematic review identified consensus
discharge planning/transfer of care interface with social care	consensus consensus
long term health and social support	consensus
visual impairment (diplopia)	consensus
physical fitness	systematic review identified
speech and language therapies aphasia	 systematic review identified

Areas to address	Evidence
apraxia	consensus
dysarthria	consensus
shoulder pain	consensus
patient information	cross refer to NICE guidance consensus

The GDG formulated new recommendations based on the consensus statements. The full Delphi report is in Appendix F

4.6 Developing recommendations

Over the course of the guideline development process, the GDG was presented with:

- Evidence tables of the clinical and economic evidence reviewed from the literature. All evidence tables are in Appendices H and I.
- Summary of clinical and economic evidence and quality (as presented in chapters –7 - 17).
- Forest plots (Appendix J).
- A description of the methods and results of the cost-effectiveness analysis undertaken for the guideline (Appendix K).

Recommendations were drafted on the basis of the GDG interpretation of the available evidence, taking into account the balance of benefits, harms and costs. When clinical and economic evidence was of poor quality, conflicting or absent, the GDG drafted recommendations based on their expert opinion. The considerations for making informal consensus based recommendations include the balance between potential harms and benefits, economic or implications compared to the benefits, current practices, recommendations made in other relevant guidelines, patient preferences and equality issues. The informal consensus recommendations were done through discussions in the GDG. The GDG may also consider whether the uncertainty is sufficient to justify delaying making a recommendation to await further research, taking into account the potential harm of failing to make a clear recommendation (See Appendix L).

The main considerations specific to each recommendation are outlined in the 'Recommendations and link to evidence sections within each chapter.

4.6.1 Research recommendations

When areas were identified for which good evidence was lacking, the guideline development group considered making recommendations for future research. Decisions about inclusion were based on factors such as:

- the importance to patients or the population
- national priorities
- potential impact on the NHS and future NICE guidance
- ethical and technical feasibility

4.6.2 Validation process

The guidance is subject to an eight week public consultation and feedback as part of the quality assurance and peer review the document. All comments received from registered stakeholders are responded to in turn and posted on the NICE website when the pre-publication check of the full

guideline occurs. Based on comments from the stakeholders during this consultation further areas were identified where guidance needed in order to address the patient pathway more comprehensively. For this reason a 'post consultation' protocol was drawn up and agreed with NICE (see section 4.5). A second consultation was then held after this extended development period.

4.6.3 Updating the guideline

Following publication, and in accordance with the NICE guidelines manual, NICE will ask a National Collaborating Centre or the National Clinical Guideline Centre to advise NICE's Guidance executive on whether the evidence base has progressed significantly to alter the guideline recommendations and warrant an update.

4.6.4 Disclaimer

Health care providers need to use clinical judgement, knowledge and expertise when deciding whether it is appropriate to apply guidelines. The recommendations cited here are a guide and may not be appropriate for use in all situations. The decision to adopt any of the recommendations cited here must be made by the practitioners in light of individual patient circumstances, the wishes of the patient, clinical expertise and resources.

The National Clinical Guideline Centre disclaims any responsibility for damages arising out of the use or non-use of these guidelines and the literature used in support of these guidelines.

4.6.5 Funding

The National Clinical Guideline Centre was commissioned by the National Institute for Health and Clinical Excellence to undertake the work on this guideline.

5 Organising health and social care for people needing rehabilitation after stroke

Rehabilitation may take place in a variety of settings, both in hospital and in the community, in out-patients and in the individual's own home. What is critical is that whatever the setting, people with stroke get access to the level of rehabilitation that meets their needs. This chapter considers the evidence for the structure of multidisciplinary stroke teams, rehabilitation units, early supported discharge and the intensity or rehabilitation.

A search for systematic reviews was carried out for stroke rehabilitation units, discharge planning, interface with social care and multidisciplinary team working. An update of a Cochrane systematic review[251] forms the basis of the recommendations regarding stroke rehabilitation services. There was a lack of direct evidence for multi-disciplinary team work, interface with social care and discharge planning (see sections 5.2, 5.3, 5.4.4). Therefore recommendations in these sections were based on modified Delphi consensus statements that were drawn up from existing national and international published guidelines. In these sections we will provide tables of Delphi statements that reached consensus and statements that did not reach consensus and give a summary of how they were used to draw up the recommendations. For details on the process and methodology used for the modified Delphi survey see Appendix F.

5.1 Stroke units

5.1.1 Evidence Review: In people after stroke, does organised rehabilitation care (comprehensive, rehabilitation and mixed rehabilitation stroke units) improve outcome (mortality, dependency, requirement for institutional care and length of hospital stay)?

Clinical Methodological Introduction	
Population	Adults and young people 16 or older who have had a stroke.
Intervention	Organised stroke units such as: • Stroke ward (including a multidisciplinary team in a discrete area caring exclusively for stroke patients). Subdivided into: o Rehabilitation stroke units (accepting patients after acute management) o Comprehensive stroke units (combined acute as well as rehabilitation) • Mixed rehabilitation ward (a multidisciplinary team including specialist nursing staff providing rehabilitation services)
Comparison	General medical ward: care in an acute medical or neurology ward without routine multidisciplinary input.
Outcomes	• Death • Death or dependency • Death or institutional care • Duration of stay in hospital or institution or both • Quality of life • Patient and carer satisfaction

5.1.1.1 Clinical Evidence Review

A search was conducted for systematic reviews comparing the clinical effectiveness of organised stroke units (comprehensive stroke units, rehabilitation stroke units, and mixed rehabilitation ward) with general medical wards to improve health outcomes for adults and young people 16 or older who have had a stroke.

One Cochrane systematic review[251] was identified. The Cochrane review originally included 31 trials (RCTs). From these trials, we excluded those that addressed an acute population (2 weeks post-stroke) and that compared mobile stroke team to general medical ward leaving 20 trials that matched our protocol. These (20) trials were included for this review.

A further systematic search was conducted for any trial published since April 2006 which was the search cut-off date of the included Cochrane review, but no studies were identified.

In the Cochrane systematic review the following strategy of analysis was adopted:

- Different types of organised stroke units were compared to general medical wards. These were:
  - Comprehensive stroke ward
  - rehabilitation stroke ward
  - mixed rehabilitation stroke ward
- Sub group analyses were carried out comparing comprehensive, rehabilitation, and mixed rehabilitation stroke wards to general medical wards for death, death or dependency, death or institutional care (median 12 months; range 6 to 12 months) and duration of stay in hospital or institution or both (**Table 10**)
- Sensitivity analysis was conducted by excluding trials with a high risk of bias. This did not affect the estimate of effect
- Length of stay was calculated in different ways (for example acute hospital stay, total stay in hospital or institution). These calculations were subject to methodological limitations
- Two trials [126] [120] extended follow-up to five and ten years post stroke (**Table 11**)
- Patient carer satisfaction and quality of life outcomes were intended as secondary outcomes but a meta-analysis was not reported

Total mortality and duration of stay in hospital or institution across all trials as well as within the different settings of organised stroke units were analysed. For this reason, in the GRADE tables we have one row for the total effect as well as three other rows for the subgroups (different settings of organised stroke unit).

The evidence statements also reflect the total effects as well as the sub-group analysis.

Please see Appendix M for excluded trials.

Table 8: Overview of stroke units compared in the Cochrane review

STUDIES	NUMBER OF PARTICIPANTS	INTERVENTION	COMPARISON	OUTCOMES
Beijing [162]; Edinburgh[90]; Goteborg-Ostra [253]; Goteborg-Sahlgren [78]; Joinville [35]; Perth [103]; Stockholm [273]; Svendborg [148]; Trondheim [120]; Umea [248]	2574 participants	Comprehensive stroke ward	General medical ward	• Death (median follow-up of 12 months; range from 6 weeks to 12 months) • *Death or dependency • **Death or

STUDIES	NUMBER OF PARTICIPANTS	INTERVENTION	COMPARISON	OUTCOMES
Dover [247]; Nottingham [126]; Orpington 1993 [128]; Orpington 1995 [129]	535 participants	Rehabilitation stroke ward	General medical ward	institutional care • Duration of stay in hospital or institution or both
Birmingham [201]; Helsinki [132]; Illinois [96]; Kuopio [239]; ; New York [81]; Newcastle [4]	630 participants	Mixed rehabilitation ward	General medical ward	

Table 9: Death; death or dependency; death or institutional care at five and 10-year follow-up

STUDIES	NUMBER OF PARTICIPANTS	INTERVENTION	COMPARISON	OUTCOMES
Nottingham [126]; Trondheim [120]	535 participants	• Rehabilitation stroke ward • Comprehensive stroke ward	General medical ward	• Death • *Death or dependency • **Death or institutional care

Note. GMW= General Medical Ward; MRW= Mixed Rehabilitation Ward; in both **Table 8** and **Table 9***Dependency is defined as a requirement for physical attention such as assistance for transfers, mobility, dressing, feeding or toileting (and where criteria for independence were approximately equivalent to a modified Rankin score of 0 to 2, a Barthel Index of more than 18 out of 20 or an Activity Index (AI) of more than 83) ; **Requirement for long-term institutional care is taken to mean care in a residential home, nursing home, or hospital at the end of scheduled follow-up.

Comparison: Organised stroke unit care versus general medical ward (median follow-up 12 months)

Table 10: Organised stroke unit care (comprehensive stroke ward, rehabilitation stroke ward and, mixed rehabilitation ward) versus general medical ward - Study references and summary of findings

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Organised stroke unit care Mean (SD)/ Frequency (%)	General medical wards Mean (SD)/ Frequency (%)	Risk ratio(RR)/ Standardised Mean Difference (SMD)/ Relative (95% CI)	Absolute effect (95% CI)	Confidence (in effect)
Death by the end of scheduled follow-up										
20 See sub-group below (next 6 rows)	RCT- single blinded	Serious limitation(a)	No serious inconsistency	No serious indirectness	No serious imprecision	374/1932 (19.40%)	410/1807 (24.10%)	RR 0.9 (0.79 to 1.01)	23 fewer per 1000 (from 48 fewer to 2 more)	Moderate
Death by the end of scheduled follow-up - Comprehensive stroke ward versus general medical ward										
10 Beijing [162]; Edinburgh [90]; Goteborg-Ostra [253]; Goteberg-Sahlgren [78]; Joinville [35]; Perth	RCT- single blinded	Serious limitation(a)	No serious inconsistency	No serious indirectness	No serious imprecision	267/1315 (20.30%)	291/1259 (23.10%)	RR 0.92 (0.8 to 1.06)	18 fewer per 1000 (from 46 fewer to 14 more)	Moderate

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Organised stroke unit care Mean (SD)/ Frequency (%)	General medical wards Mean (SD)/ Frequency (%)	Risk ratio(RR)/ Standardised Mean Difference (SMD)/ Relative (95% CI)	Absolute effect (95% CI)	Confidence (in effect)
[103]; Stockholm [273]; Svendborg [148]; Trondheim [120]; Umea [248]										
Death by the end of scheduled follow-up - Rehabilitation stroke ward versus general medical ward										
4 Dover-GMW [247]; Nottingham-GMW [126]; Orpington 1993-GMW [128]; Orpington 1995 [129]	RCT- single blinded	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	58/285 (20.40%)	68/250 (27.20%)	RR 0.77 (0.57 to 1.03)	63 fewer per 1000 (from 117 fewer to 8 more)	Low
Death by the end of scheduled follow-up - Mixed rehabilitation ward versus general medical ward										
6 Birmingha	RCT- single blinded	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision(f	49/332 (14.80%)	51/298 (17.10%)	RR 0.93 (0.66 to	12 fewer per 1000 (from 58	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Organised stroke unit care Mean (SD)/ Frequency (%)	General medical wards Mean (SD)/ Frequency (%)	Risk ratio(RR)/ Standardised Mean Difference (SMD)/ Relative (95% CI)	Absolute effect (95% CI)	Confidence (in effect)
m [201]; Helsinki [132]; Illinois [96]; Kuopio [239]; New York [81]; Newcastle [4]					)			1.31)	fewer to 53 more)	
Death or institutional care by the end of scheduled follow-up										
19 See sub-group below (next 6 rows)	RCT- single blinded	Serious limitation(a)	No serious inconsistency	No serious indirectness	No serious imprecision	695/1901 (36.60%)	746/1784 (41.80%)	RR 0.88 (0.81 to 0.95)	50 fewer per 1000 (from 21 fewer to 79 fewer)	Moderate
Death or institutional care by the end of scheduled follow-up - Comprehensive stroke ward versus general medical ward										
10 Beijing [162]; Edinburgh [90]; Goteborg-Ostra [253]; Goteberg-	RCT- single blinded	Serious limitation(a)	No serious inconsistency	No serious indirectness	No serious imprecision	477/1315 (36.30%)	511/1259 (40.60%)	RR 0.9 (0.82 to 0.99)	41 fewer per 1000 (from 4 fewer to 73 fewer)	Moderate

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Organised stroke unit care Mean (SD)/ Frequency (%)	General medical wards Mean (SD)/ Frequency (%)	Risk ratio(RR)/ Standardised Mean Difference (SMD)/ Relative (95% CI)	Absolute effect (95% CI)	Confidence (in effect)
Sahlgren [78]; Joinville [35]; Perth [103]; Stockholm [273]; Svendborg [148]; Trondheim [120]; Umea [248]										
Death or institutional care by the end of scheduled follow-up - Rehabilitation stroke ward versus general medical ward										
4 Dover-GMW [247]; Nottingham-GMW [126]; Orpington 1993-GMW [128]; Orpington 1995 [129]	RCT- single blinded	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	105/283 (37.10%)	111/250 (44.40%)	RR 0.86 (0.71 to 1.05)	62 fewer per 1000 (from 129 fewer to 22 more)	Low
Death or institutional care by the end of scheduled follow-up - Mixed rehabilitation ward versus general medical ward										

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Organised stroke unit care Mean (SD)/ Frequency (%)	General medical wards Mean (SD)/ Frequency (%)	Risk ratio(RR)/ Standardised Mean Difference (SMD)/ Relative (95% CI)	Absolute effect (95% CI)	Confidence (in effect)
5 Helsinki [132]; Illinois [96]; Kuopio [239]; New York [81]; Newcastle [4]	RCT- single blinded	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(b)	113/303 (37.30%)	124/275 (45.10%)	RR 0.82 (0.68 to 0.99)	81 fewer per 1000 (from 5 fewer to 144 fewer)	Moderate
Death or dependency by the end of scheduled follow-up										
17 See sub-group below (next 6 rows)	RCT- single blinded	Serious limitation(a)	No serious inconsistency	No serious indirectness	No serious imprecision	792/1415 (56%)	836/1346 (62.10%)	RR 0.89 (0.84 to 0.95)	68 fewer per 1000 (from 31 fewer to 99 fewer)	Moderate
Death or dependency by the end of scheduled follow- up - Comprehensive stroke ward versus general medical ward										
7 Beijing [162]; Edinburgh [90]; Goteberg-Sahlgren [78]; Joinville	RCT- single blinded	Serious limitation(a)	No serious inconsistency	No serious indirectness	No serious imprecision	448/800 (56%)	487/798 (61%)	RR 0.89 (0.82 to 0.97)	67 fewer per 1000 (from 18 fewer to 110 fewer)	Moderate

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Organised stroke unit care Mean (SD)/ Frequency (%)	General medical wards Mean (SD)/ Frequency (%)	Risk ratio(RR)/ Standardised Mean Difference (SMD)/ Relative (95% CI)	Absolute effect (95% CI)	Confidence (in effect)
[35]; Perth [103]; Trondheim [120]; Umea [248]										
Death or dependency by the end of scheduled follow-up - Rehabilitation stroke ward versus general medical ward										
4 Dover-GMW [247]; Nottingham-GMW [126]; Orpington 1993-GMW [128]; Orpington 1995 (Kalra 1995) [129]	RCT- single blinded	Serious limitation(a)	No serious inconsistency	No serious indirectness	No serious imprecision	189/283 (66.80%)	178/250 (71.20%)	RR 0.95 (0.85 to 1.06)	36 fewer per 1000 (from 107 fewer to 43 more)	Moderate
Death or dependency by the end of scheduled follow-up - Mixed rehabilitation ward versus general medical ward										
6 Birmingham [201]; Helsinki [132];	RCT- single blinded	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(b)	155/332 (46.70%)	171/298 (57.40%)	RR 0.83 (0.71 to 0.96)	98 fewer per 1000 (from 23 fewer to	Moderate

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Organised stroke unit care Mean (SD)/ Frequency (%)	General medical wards Mean (SD)/ Frequency (%)	Risk ratio(RR)/ Standardised Mean Difference (SMD)/ Relative (95% CI)	Absolute effect (95% CI)	Confidence (in effect)
Illinois [96]; Kuopio [239]; New York [81]; Newcastle [4]									166 fewer)	
Length of stay (days) in a hospital or institution (Better indicated by lower values)										
16 See sub-group below (next 6 rows)	RCT- single blinded	Serious limitation(a)	Serious inconsistency(c)	No serious indirectness	No serious imprecision	See Forest plots for study means and SDs	See Forest plots for study means and SDs	-0.09 (-0.24, 0.05)	SMD 0.09 lower (0.24 lower to 0.05 higher)	Low
Length of stay (days) in a hospital or institution - Comprehensive stroke ward versus general medical ward (Better indicated by lower values)										
10 Beijing [162]; Edinburgh [90]; Goteborg-Ostra [253]; Goteberg-Sahlgren [78]; Joinville	RCT- single blinded	Serious limitation(a)	Serious inconsistency(d)	No serious indirectness	No serious imprecision	See Forest plots for study means and SDs	See Forest plots for study means and SDs	-0.19 (-0.35, -0.02)	SMD 0.19 lower (0.35 to 0.02 lower)	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Organised stroke unit care Mean (SD)/ Frequency (%)	General medical wards Mean (SD)/ Frequency (%)	Risk ratio(RR)/ Standardised Mean Difference (SMD)/ Relative (95% CI)	Absolute effect (95% CI)	Confidence (in effect)
[35]; Perth [103]; Stockholm [273]; Svendborg [148]; Trondheim [120]; Umea [248]										
Length of stay (days) in a hospital or institution - Rehabilitation stroke ward versus general medical ward (Better indicated by lower values)										
3 Dover-GMW [247]; Nottingham-GMW [126]; Orpington 1993-GMW [128]	RCT- single blinded	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(e)	Dover-GMW: 0 (0) Nottingham-GMW: 76.72 (39.37) Orpington 1993-GMW: 0 (0)	Dover-GMW: 0 (0) Nottingham-GMW: 60.38 (48.91) Orpington 1993-GMW: 0 (0)	0.37 (0.07, 0.67)	SMD 0.37 higher (0.07 to 0.67 higher)	Moderate
Length of stay (days) in a hospital or institution - Mixed rehabilitation ward versus general ward (Better indicated by lower values)										
3 Helsinki [132]; Kuopio [239];	RCT- single blinded	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	Helsinki: 23.6 (38.8) Kuopio:	Helsinki: 30.5 (70.6) Kuopio:	0.08 (-0.21, 0.37)	SMD 0.08 higher (0.21 lower to	High

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Organised stroke unit care Mean (SD)/ Frequency (%)	General medical wards Mean (SD)/ Frequency (%)	Risk ratio(RR)/ Standardised Mean Difference (SMD)/ Relative (95% CI)	Absolute effect (95% CI)	Confidence (in effect)
Newcastle [4]						162.5 (125) Newcastle: 52 (45)	129.5 (119) Newcastle: 41 (34)		0.37 higher)	

(a) Unclear randomisation; unclear allocation concealment. Limitations were considered by study weights in the meta-analysis
(b) Confidence interval crosses one end of default MID (0.75)
(c) Heterogeneity; I^2=73%
(d) Heterogeneity; I^2=74%
(e) Confidence interval crosses one end of default MID (0.5)
(f) Confidence interval crosses both ends of default MID (0.75; 1.25)

Comparison: Comprehensive/rehabilitation stroke unit versus general medical ward (long-term follow-up)

Table 11: Comprehensive / rehabilitation stroke unit versus general medical ward - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings			Confidence (in effect)
No of	Design	Limitations	Inconsistency	Indirectness	Imprecision	Organised	General	Effect	

studies						stroke unit Mean (SD)/ Frequency (%)	medical ward Mean (SD)/ Frequency (%)	Risk ratio(RR)/ Standardised Mean Difference (SMD)/ (95% CI)	Absolute effect/ Standardised Mean Difference (SMD) (95% CI)	
Death at five-year follow-up										
2 Nottingham [126]; Trondheim [120]	RCT- single blinded	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(a)	144/286 (50.30%)	155/249 (62.20%)	RR 0.82 (0.71 to 0.95)	112 fewer per 1000 (from 31 fewer to 181 fewer)	Moderate
Death or institutional care at five-year follow-up										
2 Nottingham [126]; Trondheim [120]	RCT- single blinded	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	172/286 (60.10%)	178/249 (71.50%)	RR 0.85 (0.75 to 0.96)	107 fewer per 1000 (from 29 fewer to 179 fewer)	High
Death or dependency at five-year follow-up										
2 Nottingham [126]; Trondheim [120]	RCT- single blinded	No serious limitation	Serious inconsistency(b)	No serious indirectness	No serious imprecision	223/286 (78%)	214/249 (85.90%)	RR 0.91 (0.84 to 0.99)	77 fewer per 1000 (from 9 fewer to 138 fewer)	Moderate
Death at 10-year follow-up										
2 Nottingham [126]; Trondheim [120]	RCT- single blinded	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	205/286 (71.70%)	207/249 (83.10%)	RR 0.87 (0.79 to 0.95)	108 fewer per 1000 (from 42 fewer to 175 fewer)	High
Death or institutional care at 10-year follow-up										

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Organised stroke unit Mean (SD)/ Frequency (%)	General medical ward Mean (SD)/ Frequency (%)	Risk ratio(RR)/ Standardised Mean Difference (SMD)/ (95% CI)	Absolute effect/ Standardised Mean Difference (SMD) (95% CI)	Confidence (in effect)
2 Nottingham [126]; Trondheim [120]	RCT- single blinded	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	220/286 (76.90%)	214/249 (85.90%)	RR 0.9 (0.83 to 0.98)	86 fewer per 1000 (from 17 fewer to 146 fewer)	High
Death or dependency at 10-year follow-up										
2 Nottingham [126]; Trondheim [120]	RCT- single blinded	No serious limitation	Serious inconsistency(c)	No serious indirectness	No serious imprecision	249/286 (87.10%)	224/249 (90%)	RR 0.97 (0.91 to 1.03)	27 fewer per 1000 (from 81 fewer to 27 more)	Moderate

(a) Confidence interval crosses one end of default MID (0.75)
(b) Heterogeneity; I^2=64%
(c) Heterogeneity; I^2=51%

5.1.1.2 Economic evidence

Two studies that included the relevant comparison are reviewed[44,176]. These are summarised in the economic evidence profile below (Table 12 and QALYs not *used*

(a) Some uncertainty about applicability of non-UK resource use and unit costs
(b) Some uncertainty about applicability of resource use and unit costs from over 10 years ago
(c) Some uncertainty in interpreting the results of the analysis in terms of the health outcomes
(d) No sensitivity analysis
(e) Costing is based on the practice of one hospital so uncertainty as to whether it reflects national costs
(f) Some uncertainty about the comparability of the health outcomes in the analysis to those specified in the review protocol

Table 13). See also the full study evidence tables in Appendix I.

One study (Major, 1996[165]) that met the inclusion criteria was selectively excluded due to methodological limitations.

Table 12: Stroke units versus general medical ward care – Economic study characteristics

Study	Applicability	Limitations	Other comments
Claesson 2000[44] (Sweden)	Partially applicable (a)(b)(c)	Potentially serious limitations (e)(f)	• Cost-consequence analysis (various health outcomes) • Acute stroke units were linked to a geriatric ward for longer term rehabilitation • Within-trial analysis, clinical effectiveness data reported separately in Fagerberg 2000[78] (included in clinical review)
Moodie 2006[176] (Australia)	Partially applicable (a)(b)(d)	Very serious limitations (e)(g)	• Cost-effectiveness analysis (health outcomes = thorough adherence to defined process of care measures and rates of severe medical complications) • Stroke care unit vs. general medical ward • Within-trial analysis

(g) QALYs not used
(h) Some uncertainty about applicability of non-UK resource use and unit costs
(i) Some uncertainty about applicability of resource use and unit costs from over 10 years ago
(j) Some uncertainty in interpreting the results of the analysis in terms of the health outcomes
(k) No sensitivity analysis
(l) Costing is based on the practice of one hospital so uncertainty as to whether it reflects national costs
(m) Some uncertainty about the comparability of the health outcomes in the analysis to those specified in the review protocol

Table 13: Stroke units versus general medical ward care – Economic summary of findings

Study	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Claesson 2000[44] (Sweden)	Saves £845 (a)	No significant difference	N/A	NR
Moodie 2006[176] (Australia)	£1553 (b)	Higher adherence to process indicators and reduced rate of severe medical complications was observed on stroke units	£4891 per patient with thorough adherence gained £8116 per patient with severe complications avoided	NR

N/A = not applicable; NR=not reported
(a) Converted to UK pounds using exchange rate quoted in the study

(b) Converted to UK pounds using relevant purchasing power parities[194]

5.1.1.3 Evidence statements

Clinical evidence statements

Death by the end of scheduled follow-up

Twenty studies comprising 3739 participants found no significant difference in rate of mortality between organised stroke units (comprehensive, rehabilitation and, mixed rehabilitation wards) and general medical ward by the end of scheduled follow-up (MODERATE CONFIDENCE IN EFFECT).

Ten studies[162 90 253 78 35 103 273 148 120 248] comprising 2574 participants found no significant difference in rate of mortality between comprehensive stroke ward and general medical ward by the end of scheduled follow-up (MODERATE CONFIDENCE IN EFFECT).

Four studies [247 126 128 129] comprising 535 participants found no significant difference in rate of mortality between rehabilitation stroke ward and general medical ward by the end of scheduled follow-up (LOW CONFIDENCE IN EFFECT).

Six studies[201 132 96 239 81 4] comprising 630 participants found no significant difference in rate of mortality between mixed rehabilitation ward and general medical ward by the end of scheduled follow-up (LOW CONFIDENCE IN EFFECT).

Death or institutional care by the end of scheduled follow-up

Nineteen studies comprising 3685 participants found that significantly fewer people in the organised stroke unit (comprehensive, rehabilitation and, mixed rehabilitation wards) died or required institutional care by the end of scheduled follow-up compared to general medical ward (MODERATE CONFIDENCE IN EFFECT).

Ten studies[162 90 253 78 35 103 273 148 120 248] comprising 2574 participants found that significantly fewer people in comprehensive stroke ward died or required institutional care by the end of scheduled follow-up compared to general medical ward (MODERATE CONFIDENCE IN EFFECT).

Four studies [247 126 128 129] comprising 533 participants found no significant difference in rate of mortality or institutional care between rehabilitation stroke ward and general medical ward by the end of scheduled follow-up (LOW CONFIDENCE IN EFFECT).

Five studies[132 96 239 81 4] comprising 578 participants found that significantly fewer people in the mixed rehabilitation ward died or required institutional care by the end of scheduled follow-up compared to general medical ward (MODERATE CONFIDENCE IN EFFECT).

Death or dependency by the end of scheduled follow-up

Seventeen studies comprising 2763 participants found that significantly fewer people in organised stroke unit (comprehensive, rehabilitation and, mixed rehabilitation wards) died or were dependent by the end of scheduled follow-up compared to general medical ward (MODERATE CONFIDENCE IN EFFECT).

Seven studies[162 90 78 35 103 120 248] comprising 1598 participants found that significantly fewer people in comprehensive stroke ward died or were dependent by the end of scheduled follow-up compared to general medical ward (MODERATE CONFIDENCE IN EFFECT).

Four studies [247 126 128 129] comprising 535 participants found no significant difference in rate of mortality or dependency between the rehabilitation stroke ward and general medical ward by the end of scheduled follow-up (MODERATE CONFIDENCE IN EFFECT).

Six studies[201 132 96 239 81 4] comprising 630 participants found that significantly fewer people in the mixed rehabilitation ward died or were dependent by the end of scheduled follow-up compared to general medical ward (MODERATE CONFIDENCE IN EFFECT).

Length of stay (days) in hospital or institution

Sixteen studies comprising 3121 participants found no significant difference in length of stay (days) in hospital or institution or both between organised stroke units (comprehensive, rehabilitation, and mixed rehabilitation stroke wards) and general medical wards (LOW CONFIDENCE IN EFFECT).

Ten studies[162 90 253 78 35 103 273 148 120 248] comprising 2556 participants found a statistically significant difference in length of stay (days) in hospital or institution in favour of comprehensive stroke ward compared to general medical ward (LOW CONFIDENCE IN EFFECT).

Three studies [247 126 128]comprising 178 participants found a statistically significant difference in length of stay (days) in a hospital or institution in favour of general medical ward compared to rehabilitation stroke ward (MODERATE CONFIDENCE IN EFFECT).

Three studies[132 4,239] comprising 387 participants found no significant difference in length of stay (days) in hospital or institution between mixed rehabilitation ward and general medical ward (HIGH CONFIDENCE IN EFFECT).

Death at five-year follow-up

Two studies [126 120]comprising 535 participants found that significantly fewer people in the organised stroke unit (comprehensive and rehabilitation stroke wards) died at five-year follow-up compared to general medical ward (MODERATE CONFIDENCE IN EFFECT).

Death or institutional care at five-year follow-up

Two studies [126 120]comprising 535 participants found that significantly fewer people in the organised stroke unit (comprehensive and rehabilitation stroke ward) died or required institutional care at five-year follow-up compared to general medical ward (HIGH CONFIDENCE IN EFFECT).

Death or dependency at five-year follow-up

Two studies [126 120]comprising 535 participants found that significantly fewer people in the organised stroke unit (comprehensive and rehabilitation stroke ward) died or were dependent at five-year follow-up compared to general medical ward (MODERATE CONFIDENCE IN EFFECT).

Death at 10-year follow-up

Two studies [126 120]comprising 535 participants found that significantly fewer people in the organised stroke unit (comprehensive and rehabilitation stroke ward) died at 10-year follow-up compared to general medical ward (HIGH CONFIDENCE IN EFFECT).

Death or institutional care at 10-year follow-up

Two studies [126 120]comprising 535 participants found that significantly fewer people in the organised stroke unit (comprehensive and rehabilitation stroke ward) died or required institutional care at 10-year follow-up compared to general medical ward (HIGH CONFIDENCE IN EFFECT).

Death or dependency at 10-year follow-up

Two studies [126] [120]comprising 535 participants found no significant difference in rate of mortality or dependency between the organised stroke unit (comprehensive and rehabilitation stroke ward) and general medical ward at 10-year follow-up (MODERATE CONFIDENCE IN EFFECT).

Economic evidence statements

- One partially applicable study with potentially serious limitations showed that the costs per patient in a stroke unit was lower compared to a general medical ward with no significant difference in terms of health outcomes.
- One partially applicable study with very serious limitations showed that care on stoke units cost more than care on general medical wards. However, the quality of care delivered on stroke units was much higher.

5.1.2 Recommendations and links to evidence

Recommendation	**1. People with disability after stroke should receive rehabilitation in a dedicated stroke inpatient unit and subsequently from a specialist stroke team within the community.** **2. An inpatient stroke rehabilitation service should consist of the following:** • **a dedicated stroke rehabilitation environment** • **a core multidisciplinary team (see recommendation 3) who have the knowledge, skills and behaviours to work in partnership with people with stroke and their families and carers to manage the changes experienced as a result of a stroke.** • **access to other services that may be needed, for example:** - **continence advice** - **dietetics** - **electronic aids (for example, remote controls for doors, lights and heating, and communication aids)** - **liaison psychiatry** - **orthoptics** - **orthotics** - **pharmacy** - **podiatry** - **wheelchair services** • **a multidisciplinary education programme.**
Relative values of different outcomes	Death or dependency or institutional care were considered by the GDG to be the most critical outcomes quality of life and patient and carer satisfaction were also important outcomes. Duration of stay in hospital or institution or both, was seen as less important outcomes since such measures are often very variable and often affected by outliers. The Cochrane review reported death, admittance to institutional care and length of hospital stay as outcomes.
Trade-off between clinical benefits and harms	The GDG agreed that there is clear evidence that outcomes for patients with residual disability are better when managed in a dedicated stroke rehabilitation unit at the post two week period after stroke. This has been demonstrated both in the papers considered but also from experience in clinical practice. The GDG acknowledged that from the rehabilitation unit people would be assessed for suitability for early supported discharge or to remain on the stroke rehabilitation unit. No harms were associated with care in these units.
Economic considerations	The GDG recognised that the availability of stroke units is standard. Stroke units are expected to be more expensive than general medical ward due to provision of more specialised services and increased

	resource use for example the use of more specialised staff. An economic study showed that the costs per patient in a stroke unit was lower compared to a general medical ward with no significant difference in terms of health outcomes, while another economic study showed that care on stoke units cost more than care on general medical wards but the quality of care delivered on stroke units was much higher. The economic studies included in the economic literature review are based on single trials, whereas the NCGC clinical review pools the overall effectiveness of stroke units from several RCTs. The potential benefits (decreased mortality, decreased dependency and need for institutionalised care) of dedicated stroke units are thought to be likely to offset the costs.
Quality of evidence	The very acute stroke population (≥2 weeks post stoke) was excluded from this review because this population has already been addressed in the Stroke guideline (CG68). Those studies that addressed mobile stroke units were also excluded as the GDG agreed treatment would not be provided via this means any more. The included studies in the Cochrane review had large numbers of participants. The confidence in the effect of specified outcomes ranged from low to high with the majority being moderate. Organised stroke units showed a significant reduction in death or institutional care and death or dependency at the end of scheduled follow-up. Of the organised stroke units, the comprehensive and rehabilitation stroke ward showed a significant reduction in death; death or institutional care at five and ten-year follow-up; and a reduction in death or dependency at five-year follow-up. The evidence was found to be very robust for stroke rehabilitation units and must remain a major component for stroke care pathway.
Other considerations	Stroke rehabilitation units provide an environment for appropriate assessment for ongoing care and support for people after stroke. The definition of what a specialist stroke rehabilitation service should consist of was taken from the Stroke Unit Trialists' Collaboration outlined in the Cochrane review[251]. The GDG agreed that this was universally accepted and although the evidence comes from inpatient stroke units it is equally appropriate for early supported discharge community teams. The GDG recognised that stroke is a multifaceted condition and that access to services outside those that can be provided by a core multidisciplinary team is important. Therefore the GDG specified these in the description of the inpatient stroke rehabilitation service.

5.2 The core multidisciplinary stroke team

5.2.1 Evidence Review: What should be the constituency of a multidisciplinary rehabilitation team and how should the team work together to ensure the best outcomes for people who have had a stroke?

Population	Adults and young people 16 or older who have had a stroke
Components	• Constituency of a multidisciplinary rehabilitation team • Working practices, such as communication and co-ordination of services (team and family meetings, co-ordination of care between rehabilitation specialties and other agencies)
Outcomes	• Patient and carer satisfaction

- Optimised strategies to minimise impairment and maximise activity/participation

5.2.2 Delphi statements where consensus was achieved

Table 14: Table of consensus statements, results and comments (percentage in the results column indicates the overall rate of responders who 'strongly agreed' with a statement and 'amount of comments' in the final column refers to rate of responders who used the open ended comments boxes, i.e. No. people commented / No. people who responded to the statement)

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
	A core stroke rehabilitation team should comprise of membership from the following disciplines: Consultant neurology/stroke medicine Nursing Physiotherapy Occupational therapy Speech and Language Therapy Clinical Neuropsychology Rehabilitation Assistant Social work	 81.0 89.1 99.0 99.0 99.0 74.0 72.2 71.2	28/101 (28%) panel members commented Pharmacists and Nutritionist/Dietician did not reach consensus Some other 'optional' team members were suggested in comments, for instance: Orthoptists Counsellor Family or patient support worker Access to relevant others such as peers with stroke, information navigators, voluntary sector organisations An opinion was expressed that different specialists are required at different stages of rehabilitation ("The core team should be available although it is recognised that at different stages of the rehabilitation pathway and depending on the needs of the patient the level of these inputs may vary.") The importance of voluntary sector involvement was stated with regards to the role of a co-ordinator ("This role could be provided by the voluntary sector, the best example being the Stroke Association's information, advice and support co-ordinators.").
	Throughout the care pathway roles and responsibilities of the multi-disciplinary stroke rehabilitation team services should be clearly outlined, documented and communicated to the patient and their family.	72.7	18/99 (18%) panel members commented Information to the family of the person who has had a stroke should

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
			only be given with patient's consent Communication was viewed as integral in rehabilitation process Extracts: 'Verbal communication should be supported by clear, unambiguous written information to avoid any subsequent disputes/confusion.' 'I think it helps communication for patients and staff, however the frequency and process of this has to be realistic in its delivery.'
	In order to inform and direct further assessment, members of the MDT should screen the person who has had a stroke for a range of impairments and disabilities.	81.0	9/100 (9%) commented: Reliability and validity of screening instruments was highlighted Reason for screening: Screening to inform treatment / further assessment rather than screening for screening's sake Treatment: Some people commented that the focus in stroke rehabilitation should be on treatment rather than measurement.

5.2.3 Delphi statement where consensus was not reached

Table 15: Table of 'non-consensus' statements with qualitative themes of panel comments

Number	Statement	Results	Amount and content of panel comments – or themes
1.	The person who has had a stroke is integrated in the stroke rehabilitation team.	62.9	26/100 (26%) panel members commented in round 2; 29/84 (35%) commented in round 3 and 24/70 (34%) commented in round 4: **Impairments** of the persons who have had a stroke that affect participation should be considered for this statement. ("Some individuals can easily make a very active and substantial contribution to the work of the team whereas others because of the severity of the stroke or of any communication

Number	Statement	Results	Amount and content of panel comments – or themes
			difficulties would be much more limited.") **Patient preference**: It may not be the wish of the person who has had a stroke to participate in the team ("When I need care or help I wish to be treated with respect, dignity and as an equal, but I view the MDT as people who support me, advise me and have clinical expertise, they are the team who help me."). Between rounds 3 and 4 the **statement was changed** from: 'is a **member** of' to 'is **integrated** in' the stroke rehabilitation team'. Most panel members **objected** to the **concept of team membership.** The concept of **membership** as opposed to partnership was highlighted Two panel members expressed the opinion that this statement was redundant.
2.	A member of the multidisciplinary stroke rehabilitation team should be tasked with coordination and steering (for example communication, family liaison and goal planning) of the rehabilitation of the person who has had a stroke at each stage of the care pathway.	62.5	A direct prompt was given for this question (to list the roles). In round 2 61/100 (61%) panel members commented; 48/85(56%) in round 3 and 34/72 (47%) in round 4: There was a **list of possible roles** for a coordinator: • Communication • Goal planning • Family liaison • Key working • Discharge planning • Single point of contact "few teams cover the whole of the stroke care pathway and this would not work practically". "where a member of the team is

Number	Statement	Results	Amount and content of panel comments – or themes
			responsible, the process becomes slowed down."

5.2.4 Recommendations and links to Delphi consensus survey

Statements	1. A core stroke rehabilitation team should comprise of membership from the following disciplines: • Consultant neurology/stroke medicine • Nursing • Physiotherapy • Occupational therapy • Speech and Language Therapy • Clinical Neuropsychology • Rehabilitation assistant • Social worker 2. Throughout the care pathway roles and responsibilities of the multi-disciplinary stroke rehabilitation team services should be clearly outlined, documented and communicated to the patient and their family. 3. In order to inform and direct further assessment, members of the MDT should screen the person who has had a stroke for a range of impairments and disabilities.
Recommendations	**3. A core multidisciplinary stroke rehabilitation team should comprise the following professionals with expertise in stroke rehabilitation:** • **consultant physicians** • **nurses** • **physiotherapists** • **occupational therapists** • **speech and language therapists** • **clinical psychologists** • **rehabilitation assistants** • **social workers.** **4. Throughout the care pathway, the roles and responsibilities of the core multidisciplinary stroke rehabilitation team should be clearly documented and communicated to the person and their family or carer.** **5. Members of the core multidisciplinary stroke team should screen the person with stroke for a range of impairments and disabilities, in order to inform and direct further assessment and treatment.**
Other considerations	Some concern was expressed that as a result of the Delphi survey the patient and family members were not part of the MDT (one of

the statements that did not reach consensus). A lot of comments had been made on this within the survey, and the GDG thought it may be because of different interpretations of the meaning of the term 'team'. The MDT is made up of a group of professionals who are employed to deliver a service, and although the patient and family members would be involved they would not be considered as an intrinsic part of the team delivering a rehabilitation service. It was agreed that it was important that the patient is clear what the team's function is and what each individual role does. The GDG acknowledged that there is a lack of information for patients and their families on the structure of the stroke pathway, and on individual team member's responsibilities. It is often just assumed patients already have an understanding of what rehabilitation services are.

It was therefore felt that documenting and communicating this was very important. There was a discussion of whether it was possible to provide a clearer description of how this would take place in practice. However, the GDG came to the conclusion that there would be a wide variation depending on where in the care pathway people would be, and according to individual difficulties and priorities. The GDG therefore did not want to be too prescriptive about this process.

The group acknowledged that whilst stating a clinical neuro-psychologist would be the ideal, it was not realistic as there were not enough of these professionals currently available. Therefore a recommendation for a clinical psychologist was made. However the group were in strong agreement that psychological services should be a core part of the MDT and this was not always the case at present. Although consensus was reached for a consultant neurologist/stroke medicine this was modified by the group in recognition that stroke medicine in this country is one year training and physicians come from a variety of different host routes.

The GDG recognised that there were a range of other services that people may require after a stroke, not covered by the core MDT, but vital in providing a comprehensive service. The GDG also raised the importance of providing guidance on access to a range of services that may be required and the importance of speedy referral to other health professional expertise such as dieticians, continence advisors, orthoptists, orthotists or pharmacy. A recommendation was therefore included providing guidance on access to services outside the core team based on comments from the Delphi panel (see recommendation 2).

5.3 Health and social care interface

5.3.1 Delphi statements where consensus was achieved

Table 16: Table of consensus statements, results and comments (percentage in the results column indicates the overall rate of responders who 'strongly agreed' with a statement and 'amount of comments' in the final column refers to rate of responders who used the open ended comments boxes, i.e. No. people commented / No. people who responded to the statement)

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
1.	Where appropriate, social workers should be involved with the stroke rehabilitation team in the assessment of post hospital care needs.	72.0	11/100 (11%) panel members commented The panel assumed that a social worker would be part of the MDT Some people thought that the term 'appropriate' needed to be defined.
2.	The role of social care and any service provision required should be discussed with the person who has had a stroke and documented within the social care plan.	72.7	10/99 (10%) panel members commented A few panel members highlighted the relationship between this statement and the joint care plan and that there should be access to one set of notes. A couple of people thought that this should be discussed fully with the person who has had a stroke and with the carer or nearest relative. In another comment it was stated that it is not necessary to discuss the whole plan with the person who has had a stroke in case the amount of information was overwhelming
3.	When social needs are identified there needs to be timely involvement of social services to ensure seamless transfer from primary to community care.	76.8	11/100 (11%) panel members commented Several panel members commented that a social worker should be part of the MDT. One person commented whether the statement should read 'from secondary to community care' rather than 'from primary to community care'.

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
			Another comment was regarding the concepts of 'timely' and 'seamless' which were not defined and the statement should be set out to describe minimum standards.
4.	Coordination between health and social care should include a timely, accurate assessment (including documentation and communication) to facilitate the transitional process for admission/return to care or nursing homes.	77.8	10/99 (10%) panel members commented This should also include the management staff of the care home. Social worker should be part of the MDT. There would be no need for this since integrated health and social care teams would deal with this. The term 'timely' was questioned.
5.	Should family members wish to participate in the care of the person who has had a stroke; they should be offered training in assisting the person who has had a stroke in their activities of daily living prior to discharge.	79.8	18/99 (18%) panel members commented There were some comments about the need for consent from the person who has had a stroke. The difficulty of arranging this prior to discharge was mentioned and whether this could be done at the person's home was raised. It was also stated that there should not be an assumption that people are willing to provide high levels of care. Respite care and carer support options should also be identified and put in place.

5.3.2 Recommendations and links to Delphi consensus survey

Statements	4. Where appropriate, social workers should be involved with the stroke rehabilitation team in the assessment of post hospital care needs. 5. The role of social care and any service provision required should be discussed with the person who has had a stroke and documented within the social care plan.

	6. When social needs are identified there needs to be timely involvement of social services to ensure seamless transfer from primary to community care. 7. Coordination between health and social care should include a timely, accurate assessment (including documentation and communication) to facilitate the transitional process for admission/return to care or nursing homes. 8. Should family members wish to participate in the care of the person who has had a stroke; they should be offered training in assisting the person who has had a stroke in their activities of daily living prior to discharge. If there is a new identified need for further stroke rehabilitation services, the person who has had a stroke should be able to self-refer with the support of a GP or specialist community services.
Recommendations	For recommendations on long-term health and social support see 15.2.4. **6. Health and social care professionals should work collaboratively to ensure a social care assessment is carried out promptly, where needed, before the person with stroke is transferred from hospital to the community. The assessment should:** • **identify any ongoing needs of the person and their family or carer, for example, access to benefits, care needs, housing, community participation, return to work, transport and access to voluntary services.** • **be documented and all needs recorded in the person's health and social care plan, with a copy provided to the person with stroke.** **7. Offer training in care (for example, in moving and handling and helping with dressing) to family members or carers who are willing and able to be involved in supporting the person after their stroke.** • **Review family members' and carers' training and support needs regularly (as a minimum at the person's 6-month and annual reviews), acknowledging that these needs may change over time.**
Economic considerations	There are some costs associated with the social care assessment and with the training for family members (staff time cost). The GDG has considered the economic implications and concluded that these interventions will improve the quality of life of the person with stroke; the improvement in quality of life was considered likely to outweigh the costs.
Other considerations	A social care assessment to identify needs to support the person and carers following discharge is essential, and the benefits of having a social worker as part of the multidisciplinary stroke rehabilitation team has been acknowledged. It was agreed having social care fully integrated within the MDT helps to ensure information is communicated and planning support for discharge is conducted adequately. It was recognised that there is often a deficiency in the provision of a co-

	ordinated approach to delivery of services in current practice. An assessment may be required at different points of the care pathway and include other settings such as care homes. The discussion also highlighted a need for more joined up service provision and need for speedy distribution of information / documentation between services. Communication is currently commonly slow which then leads to delays and in the rehabilitation process. The GDG also agreed that the person who has had a stroke and their family / carer need to be fully integrated in this process and as such receive a copy of the health and social care plan. Provision of training for the carer who is willing and able to provide support has been highlighted. It was agreed that these needs would vary at different stages of the person's recovery, and therefore should be reviewed at regular intervals. The GDG agreed that training and support for carers was extremely important.

5.4 Transfer of care from hospital to community

Rehabilitation can take place in either the hospital or at home. There are potential advantages to rehabilitation at home including interventions targeted more accurately at the patients' needs within their own environment, better patient and carer outcomes in terms of well-being and mood, and greater cost-effectiveness. There are also potential disadvantages, for example, delivering high intensity therapy may be more difficult to organise in a community setting.

5.4.1 Early supported discharge

Early supported discharge is an approach that promotes discharge from hospital for community based rehabilitation as soon as possible once appropriate support is in place for both patient and carer. It is likely that some stroke patients will be unsuitable for this ESD approach because of their level of physical disability or because of significant prior morbidity. The components of early supported discharge vary from service to service, the integrated health and social care inputs offered, and varying skill mix and number. Identifying the clinical and cost effectiveness of ESD is thus complex and multifaceted.

5.4.2 Evidence Review: In people after stroke what is the clinical and cost-effectiveness of early supported discharge versus usual care?

Clinical Methodological Introduction	
Population	Adults and young people 16 or older who have had a stroke
Intervention	Early supported discharge for stroke
Comparison	Usual care; stroke hospital units
Outcomes	• Barthel Index • Length of hospital stay • Functional Independence Measure (FIM) • Caregiver strain index • Falls • Readmissions to hospital • Hospital Anxiety and Depression Scale (HADS)

Clinical Methodological Introduction	
	• Mortality • Quality Of Life (any outcome) • Nottingham Extended Activities of Daily Living (NEADL)

5.4.2.1 Clinical evidence review

Searches were conducted for systematic reviews and RCTs comparing the effectiveness of early supported discharge versus usual care for patients with stroke. Only studies with a minimum sample size of 20 participants (10 in each arm) were selected. Ten (10) RCTs were identified. **Table 17** summarises the population, intervention, comparison and outcomes for each of the studies.

Table 17: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix H.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOME
Anderson, 2000[10]	Acute stroke patients that were medically stable and suitable to be discharged early from hospital to a community rehabilitation scheme and had sufficient physical and cognitive function. Patients included in this study were mildly disabled[277]	Early hospital discharge and individually tailored home-based/community rehabilitation (median duration, 5 weeks) by a full time occupational therapist, a consultant in rehabilitation, physiotherapists, occupational therapists, social workers, speech therapists, and rehabilitation nurses. Efforts were made so that discharge from hospital could occur within 48 hours of randomisation. (N=42) Barthel Index at randomisation [median (IQR)]: 85 (80-97)	Conventional care and rehabilitation in hospital, either on an acute-care medical geriatric ward or in a multidisciplinary stroke rehabilitation unit run by specialists in rehabilitation or geriatric medicine. (N=44) Barthel Index at randomisation [median (IQR)]: 86 (77-95)	• SF-36 • Mortality • Falls • Barthel index • Caregiver strain index • Readmission to hospital • Length of hospital stay
Askim, 2004[12]	Acute stroke patients with a Scandinavian Stroke Scale (SSS) score greater than 2 points and less than 58 points. I score such as this indicates that	Extended service consisting of stroke unit treatment combined with a home based programme of follow-up care co-ordinated by a mobile stroke team that offers early supported discharge and works in close co-operation with the	Ordinary service defined as the stroke unit treatment of choice according to evidence-based recommendations. (N=31) Barthel index, mean/median: 54.0/55.0	• Barthel Index • Caregiver Strain index • Mortality • Length of hospital stay

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOME
	patients were moderately disabled[277]	primary health care system during the first four weeks after discharge. The mobile team consisted of a nurse, a physiotherapist, an occupational therapist and the consulting physician. (N=31) Barthel index, mean/median: 57.7/55.0		
Bautz-Holtert, 2002[20]	Acute stroke patients; not severely disabled prior to stroke; had no other medical condition likely to preclude rehabilitation and were medically stable. Patients included were moderately to mildly disabled[277]	Early supported discharge with a multidisciplinary team for each stroke patient was offered and support and supervision was provided from the project team whenever needed. Four weeks after discharge, the patients in the ESD group were seen at the outpatient clinic. (N=42) Barthel Index sum score at day 7: [median (IQR)]: 16.5 (12-19)	Conventional procedures for discharge and continued rehabilitation, which were anticipated to be less well organized. (N=40) Barthel Index sum score at day 7: [median (IQR)]: 14 (11-18)	• Length of hospital stay • Nottingham Extended Activities of Daily Living • Mortality
Donnelly, 2004[69]	Acute stroke patients with no pre-existing physical or mental disability that was judged to make further rehabilitation inappropriate. Patients included were moderately (10-14) to mildly disabled (15-19)[277]	Earlier hospital discharge combined with community-based multidisciplinary stroke team rehabilitation comprising 0.33 coordinator, 1 occupational therapist, 1.5 physiotherapists, 1 speech and language therapist, and 2 rehabilitation assistants. On average the number of home visits over a 3-month period was 2.5 per week each lasting 45 minutes.	Usual hospital rehabilitation comprising inpatient rehabilitation in a stroke unit and follow-up rehabilitation in a day hospital (N=54) Barthel Index at baseline: mean (SD): 13.89 (3.93); Median (range): 15 (16)	• Barthel Index • Nottingham Activities of Daily Living • SF-36 • EuroQoL • Caregiver Strain index • Length of stay

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOME
		Patients in the CST group were to be discharged as soon as their home was assessed. (N=59) Barthel Index at baseline: mean (SD): 14.14 (3.38); Median (range): 14 (13)		
[f]Fjaeartoft, 2004[82]	Acute stroke patients with a Scandinavian Stroke Scale (SSS) score greater than 2 points and less than 57 points (i.e. moderately disabled).	Extended Stroke Unit Service (ESUS) defined as stroke unit treatment similar to OSUS combined with service from a mobile team that offers early supported discharge and coordinates further rehabilitation and follow-up in close cooperation with the primary healthcare system. The team consisted of a nurse, a physiotherapist, an occupational therapist, and a physician. (N=160)	Ordinary Stroke Unit Service (OSUS) consisting of treatment in a combined acute and rehabilitation stroke unit and/or the primary healthcare system. Also defined as stroke unit treatment according to evidence-based recommendations. (N=160)	• Caregiver strain index • Global Nottingham Health Profile 1&2
Indredavik, 2000[121]	Acute stroke patients with a Scandinavian Stroke Scale (SSS) score greater than 2 points and less than 57 points. Patients included were moderately disabled[277]	Extended Stroke Unit Service (ESUS) defined as stroke unit treatment similar to OSUS combined with service from a mobile team that offers early supported discharge and coordinates further rehabilitation and follow-up in close cooperation with the primary healthcare system. The team consisted of a nurse, a physiotherapist, an occupational therapist, and a physician. (N=160) Barthel Index, mean/median:	Ordinary Stroke Unit Service (OSUS) consisting of treatment in a combined acute and rehabilitation stroke unit and/or the primary healthcare system. Also defined as stroke unit treatment according to evidence-based recommendations. (N=160) Barthel Index, mean/median: 58.5/60	• Barthel Index • Mortality

[f] 12 month quality of life follow-up on Indredavik study

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOME
		60.4/65.0		
Mayo, 2000[170]	Acute stroke patients with motor deficits after stroke who had caregivers willing and able to provide live-in care for the subject over a 4-week period after discharge from the hospital. Patients included were mildly disabled[277]	Rehabilitation at home after prompt discharge from hospital with the immediate provision of follow-up services by a multidisciplinary team offering nursing, physical therapy (PT), occupational therapy (OT), speech therapy (ST), and dietary consultation. Duration of intervention was 4 weeks for all participants. (N=58) Barthel Index: 84±14.4	Usual care practices for discharge planning and referral for follow-up services. These included physiotherapy, occupational therapy and speech therapy, as requested by the patient's care provider and offered through extended acute-care hospital stay; inpatient or outpatient rehabilitation; or home care via local community health clinics (N=56) Barthel Index: 82.7±13.9	• SF-36 • Barthel Index
Rodgers, 1997[219]	Acute stroke patients that were not severely handicapped prior to the incident stroke with no other condition likely to preclude rehabilitation. Patients included were moderately disabled[277]	Early Supported Discharge with home care from the Stroke Discharge Team (community based). The team consisted of an occupational therapist, physiotherapist, speech and language therapist, social worker and occupational therapy technician. The stroke discharge rehabilitation service was available five days per week but the home care component of the service was available 24h per day and seven days per week if required. The stroke discharge service was withdrawn gradually and a contact name and number was provided to patients in case of subsequent queries or problems (N=46)	Inpatient and outpatient care was provided for the control group by conventional hospital and community services. Discharge planning and services post discharge for patients randomized to conventional care were arranged and provided according to the usual practice of each participating ward or unit. (N=46) Barthel Index at 7 days post stroke: [median (range)]: 13 (2-20)	• Length of hospital stay • Mortality • Nottingham Extended Activities of Daily Living • Readmission to hospital

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOME
		Barthel Index at 7 days post stroke: [median (range)]: 15 (2-20)		
Rudd, 1997[224]	Stroke patients able to perform functional independent transfer or able to perform transfer with assistance	Early discharge with a planned course of domiciliary physiotherapy, occupational therapy, and speech therapy, with visits as frequently as considered appropriate (maximum one day visit from each therapist) for up to 3 months after randomization. (N=167) Barthel score at randomisation ranged from 0-20	Usual care with no augmentation of social services resources. (N=164) Barthel score at randomisation ranged from 0-20	• Barthel Index • Hospital Anxiety and Depression Scale (HADS), • Caregiver strain index • Mortality
von Koch 2000[275]	Stroke patients with moderate to severe impairment	Early supported discharge and continued rehabilitation at home by a specialised team. The rehabilitation programme was tailor-made for each patient, continued in their homes for 3 to 4 months (mean of 12 visits (range 3-31) by a home rehabilitation team therapist). (N=42)	Routine rehabilitation. (N=41)	• Barthel Index • Falls • Length of hospital stay • Readmission to hospital

Comparison of early supported discharge versus usual care

Table 18: Early supported discharge versus usual care - clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
								Effect		
Author(s)	Design	Limitations	Inconsistency	Indirectness	Imprecision	Early Supported Discharge Mean (SD)/ Median (range)/frequency (%)	Usual care Mean (SD)/ Median (range)/ Frequency (%)	Mean difference/ Median difference/ SMD/Risk Ratio (95% CI)	Absolute effect/ Mean Difference (MD) or Standardised Mean Difference (SMD) (95% CI) or P value	Confidence (in effect)
Barthel Index (6 weeks follow-up) (Better indicated by higher values)										
Askim, 2004[12]	RCT	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (d)	75.2 (30.6)	74 (31.2)	1.20 (-14.71 to 17.11)	MD 1.20 higher (14.71 lower to 17.11 higher)	Moderate
Barthel Index (12 weeks follow-up) (Better indicated by higher values)										
Mayo, 2000[170]	RCT	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision (d)	97.1 (6.9)	95.1 (10.6)	2.0 (-1.72 to 5.72)	MD 2.0 higher (1.72 lower to	Low

Quality assessment						Summary of findings				
								Effect		
Author(s)	Design	Limitations	Inconsistency	Indirectness	Imprecision	Early Supported Discharge Mean (SD)/ Median (range)/frequency (%)	Usual care Mean (SD)/ Median (range)/ Frequency (%)	Mean difference/ Median difference/ SMD/Risk Ratio (95% CI)	Absolute effect/ Mean Difference (MD) or Standardised Mean Difference (SMD) (95% CI) or P value	Confidence (in effect)
									5.72 higher)	
Barthel Index (26 weeks follow-up) (Better indicated by higher values)										
Anderson, 2000[10],	RCT	Serious limitations(c)	No serious inconsistency	No serious indirectness	(m)	96.0 (88.3-100)(h)	98.0 (85.5-100)(h)	0 (-2.0 to 2.0)(h)	(n)	Moderate (m)
Barthel Index (26 weeks follow-up) (Better indicated by higher values)										
Askim, 2004[12]	RCT	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (d)	75 (32.9)	77.7 (27.6)	-2.70 (-19.59 to 14.19)	MD 2.70 lower (19.59 lower to 14.19 higher)	Moderate
Barthel Index (52 weeks follow-up) (Better indicated by higher values)										
Askim, 2004[12]; Donnelly, 2004[69];	RCTs	Serious limitations(	No serious inconsistency	No serious indirectness	Serious imprecision	Askim: 71.7	Askim: 79.0	0.03 (-0.16 to 0.22)	SMD 0.03	Low

Quality assessment						Summary of findings				
								Effect		
Author(s)	Design	Limitations	Inconsistency	Indirectness	Imprecision	Early Supported Discharge Mean (SD)/ Median (range)/frequency (%)	Usual care Mean (SD)/ Median (range)/ Frequency (%)	Mean difference/ Median difference/ SMD/Risk Ratio (95% CI)	Absolute effect/ Mean Difference (MD) or Standardised Mean Difference (SMD) (95% CI) or P value	Confidence (in effect)
Rudd, 1997[224]		b)			(d)	(34.7); Donnelly: 17.98 (3.1); Rudd: 16.0 (4.0)	(28.7); Donnelly: 17.15 (3.81); Rudd: 16.0 (4.0)		higher (0.16 lower to 0.22 higher)	
Barthel Index (26 weeks follow-up) (Better indicated by higher values)										
Indredavik, 2000[121]	RCT	No serious limitations	No serious inconsistency	No serious indirectness	(f)	(g)	(g)	1.72 (1.10-2.70)(h)	(g)	Moderate (f)
Barthel Index (52 weeks follow-up) (Better indicated by higher values)										
von Koch, 2000[275]	RCT	No serious limitations	No serious inconsistency	No serious indirectness	(f)	(g)	(g)	2.75 (0.77-9.77)(h)	(g)	Moderate (f)

Quality assessment						Summary of findings				
								Effect		
Author(s)	Design	Limitations	Inconsistency	Indirectness	Imprecision	Early Supported Discharge Mean (SD)/ Median (range)/frequency (%)	Usual care Mean (SD)/ Median (range)/ Frequency (%)	Mean difference/ Median difference/ SMD/Risk Ratio (95% CI)	Absolute effect/ Mean Difference (MD) or Standardised Mean Difference (SMD) (95% CI) or P value	Confidence (in effect)
Falls (24 and 52 weeks follow-up) (Better indicated by lower values)										
Anderson, 2000[10]; von, 2000[275]	RCT	Serious limitations(c)	no serious inconsistency	no serious indirectness	Very serious imprecision (e)	31/84 (36.9 %)	32/85 (37.6 %)	RR 0.96 (0.68 to 1.35)	15 fewer per 1000 (from 120 fewer to 132 more)	Very low
Length of hospital stay (6 months follow-up) (Better indicated by lower values)										
Anderson, 2000[10]	RCT	Serious limitations(c)	No serious inconsistency	No serious indirectness	(m)	15.0 (8.0-22.0)	30.0 (17.3-48.5)	-13.0 (-22.0 to -6.0)	<0.001(h)	Moderate (m)
Length of hospital stay (6 months follow-up) (Better indicated by lower values)										
Bautz-Holtert, 2002[20]	RCT	Serious limitations(a	No serious inconsistency	No serious indirectness	(m)	22(h)	31(h)	(n)	(n)	Moderate (m)

Quality assessment						Summary of findings				
								Effect		
Author(s)	Design	Limitations	Inconsistency	Indirectness	Imprecision	Early Supported Discharge Mean (SD)/ Median (range)/frequency (%)	Usual care Mean (SD)/ Median (range)/ Frequency (%)	Mean difference/ Median difference/ SMD/Risk Ratio (95% CI)	Absolute effect/ Mean Difference (MD) or Standardised Mean Difference (SMD) (95% CI) or P value	Confidence (in effect)
		)								
Length of hospital stay (6 months follow-up) (Better indicated by lower values)										
von Koch 2000[275]	RCT	Serious limitations(a)	No serious inconsistency	No serious indirectness	(o)	6(h)	6(h)	(o)	(o)	Moderate (o)
Length of hospital stay (52 weeks follow-up) (Better indicated by lower values)										
Askim, 2004[12]; Mayo, 2000[170]; Rudd, 1997[224]	RCT	Serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	Askim: 23.5 (30.5); Mayo: 9.8 (5.3); Rudd: 12 (19)	Askim: 30.5 (44.8); Mayo: 12.4 (7.4); Rudd: 18 (24)	-3.34 (-5.44, -1.24)	MD 3.34 lower (5.44 to 1.24 lower)	Moderate
Length of hospital stay (52 weeks follow-up) (Better indicated by lower values)										
Donnelly,	RCT	Serious	No serious	No serious	Very serious	(l)	(l)	-8.00 (-23.25,	MD 8	Very low

Quality assessment						Summary of findings				
								Effect		
Author(s)	Design	Limitations	Inconsistency	Indirectness	Imprecision	Early Supported Discharge Mean (SD)/ Median (range)/frequency (%)	Usual care Mean (SD)/ Median (range)/ Frequency (%)	Mean difference/ Median difference/ SMD/Risk Ratio (95% CI)	Absolute effect/ Mean Difference (MD) or Standardised Mean Difference (SMD) (95% CI) or P value	Confidence (in effect)
2004[69]		limitations(b)	inconsistency	indirectness	imprecision (k)			7.25)	lower (23.25 lower to 7.25 higher)	
Length of hospital stay (52 weeks follow-up) (Better indicated by lower values)										
Rodgers, 1997[219]	RCT	Serious limitations(q)	No serious inconsistency	No serious indirectness	(m)	14 (8-31)(h)	23 (11-58) (h)	(n)	0.03(h)	Moderate (m)
Mortality (12 - 52 weeks follow-up)										
Anderson, 2000[10], Askim, 2004[12]; Bautz-Holter, 2002[20]; Indredavik,	RCT	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (i)	49/444 (10.1 %)	65/482 (10.1 %)	RR 0.75 (0.53 to 1.05)	34 fewer per 1000 (from 63 fewer to 7 more)	Low

Quality assessment						Summary of findings				
								Effect		
Author(s)	Design	Limitations	Inconsistency	Indirectness	Imprecision	Early Supported Discharge Mean (SD)/ Median (range)/frequency (%)	Usual care Mean (SD)/ Median (range)/ Frequency (%)	Mean difference/ Median difference/ SMD/Risk Ratio (95% CI)	Absolute effect/ Mean Difference (MD) or Standardised Mean Difference (SMD) (95% CI) or P value	Confidence (in effect)
2000[121]; Rodgers, 1997[219]; Rudd, 1997[224]										
Nottingham ADL (3 months follow-up) (Better indicated by higher values)										
Bautz-Holtert, 2002[20]	RCT	Serious limitations (a)	No serious inconsistency	No serious indirectness	(m)	34.5 (28-44)	30 (14-46)	(-8 to 7)(h)	0.78(h)	Moderate(m)
Nottingham ADL (6 months follow-up) (Better indicated by higher values)										
Bautz-Holtert, 2002[20]	RCT	Serious limitations (a)	No serious inconsistency	No serious indirectness	(m)	40 (29-45)(h)	37 (20-46)(h)	(-8 to 7)(h)	0.93(h)	Moderate(m)
Nottingham ADL (52 weeks follow-up) (Better indicated by higher values)										
Donnelly, 2004[69]	RCT	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (j)	12.0 (6.34)	10.43 (5.92)	1.57 (-0.87 to 4.01)	MD 1.57 higher (0.87 lower to	Moderate

Quality assessment						Summary of findings				
								Effect		
Author(s)	Design	Limitations	Inconsistency	Indirectness	Imprecision	Early Supported Discharge Mean (SD)/ Median (range)/frequency (%)	Usual care Mean (SD)/ Median (range)/ Frequency (%)	Mean difference/ Median difference/ SMD/Risk Ratio (95% CI)	Absolute effect/ Mean Difference (MD) or Standardised Mean Difference (SMD) (95% CI) or P value	Confidence (in effect)
									4.01 higher)	
Nottingham ADL (52 weeks follow-up) (Better indicated by higher values)										
Rodgers, 1997[219]	RCT	Serious limitations(q)	No serious inconsistency	No serious indirectness	(m)	10.0 (0-18)	7.0 (0-21)	(n)	(n)	Moderate(m)
Readmission to hospital (24&52 weeks follow-up) (Better indicated by lower values)										
Anderson, 2000[10]; Rodgers, 1997[219]; von Koch 2000[275]	RCT	Serious limitations (c,q)	No serious inconsistency	No serious indirectness	Very serious imprecision (e)	30/128 (23.4%)	26/128 (17.8%)	RR 1.16 (0.73 to 1.82)	32 more per 1000 (from 55 fewer to 167 more)	Very low
SF-36 - Anderson - Physical functioning (24 weeks follow-up) (Better indicated by higher values)										
Anderson, 2000[10]	RCT	Serious limitations(c	No serious inconsistency	No serious indirectness	No serious imprecision	41.3 (29.1)	42.5 (28.1)	-1.2 (-13.3 to 10.9)	MD 1.2 lower	Moderate

Quality assessment						Summary of findings				
								Effect		
Author(s)	Design	Limitations	Inconsistency	Indirectness	Imprecision	Early Supported Discharge Mean (SD)/ Median (range)/frequency (%)	Usual care Mean (SD)/ Median (range)/ Frequency (%)	Mean difference/ Median difference/ SMD/Risk Ratio (95% CI)	Absolute effect/ Mean Difference (MD) or Standardised Mean Difference (SMD) (95% CI) or P value	Confidence (in effect)
		)							(13.3 lower to 10.9 higher)	
SF-36 - Anderson - Social functioning (24 weeks follow-up) (Better indicated by higher values)										
Anderson, 2000[10]	RCT	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision(j)	74.7 (31.3)	82.8 (23.8)	-8.1 (-19.89 to 3.69)	MD 8.1 lower (19.89 lower to 3.69 higher)	Low
SF-36 - Physical health (12 weeks follow-up) (Better indicated by higher values)										
Mayo, 2000[170]	RCT	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision (j)	42.9 (10.1)	37.9 (10.6)	5 (0.82 to 9.18)	MD 5 higher (0.82 to 9.18 higher)	Low

Quality assessment						Summary of findings				
								Effect		
Author(s)	Design	Limitations	Inconsistency	Indirectness	Imprecision	Early Supported Discharge Mean (SD)/ Median (range)/frequency (%)	Usual care Mean (SD)/ Median (range)/ Frequency (%)	Mean difference/ Median difference/ SMD/Risk Ratio (95% CI)	Absolute effect/ Mean Difference (MD) or Standardised Mean Difference (SMD) (95% CI) or P value	Confidence (in effect)
SF-36 - Mental health (12 weeks follow-up) (Better indicated by higher values)										
Mayo, 2000[170]	RCT	Serious limitations(a)	No serious inconsistency	No serious indirectness	No serious imprecision	46.5 (11.7)	46.7 (10.8)	-0.2 (-4.73 to 4.33)	MD 0.2 lower (4.73 lower to 4.33 higher)	Moderate
SF-36 - Physical health (52 weeks follow-up) (Better indicated by higher values)										
Donnelly, 2004[69]	RCT	No serious limitations	No serious inconsistency	No serious indirectness	No serious imprecision	35.59 (31.32)	34.67 (32.01)	0.92 (-11.71 to 13.55)	MD 0.92 higher (11.71 lower to 13.55 higher)	High
SF-36 - Mental health (52 weeks follow-up) (Better indicated by higher values)										
Donnelly, 2004	RCT	No serious	No serious	No serious	Serious	69.49	67.3	2.19 (-5.48 to	MD 2.19	Moderate

Quality assessment						Summary of findings				
								Effect		
Author(s)	Design	Limitations	Inconsistency	Indirectness	Imprecision	Early Supported Discharge Mean (SD)/ Median (range)/frequency (%)	Usual care Mean (SD)/ Median (range)/ Frequency (%)	Mean difference/ Median difference/ SMD/Risk Ratio (95% CI)	Absolute effect/ Mean Difference (MD) or Standardised Mean Difference (SMD) (95% CI) or P value	Confidence (in effect)
[69]		limitations	inconsistency	indirectness	imprecision (j)	(18.26)	(20.07)	9.86)	higher (5.48 lower to 9.86 higher)	
EuroQol (52 weeks follow-up) (Better indicated by higher values)										
Donnelly, 2004 [69]	RCT	No serious limitations	No serious inconsistency	No serious indirectness	No serious imprecision	66.36 (18.45)	68.21 (20.31)	-1.85 (-9.60 to 5.90)	MD 1.85 lower (9.60 lower to 5.90 higher)	High
Global Nottingham Health Profile 1 (52 weeks follow-up) (Better indicated by higher values)										
Fjaeartoft, 2004[82]	RCT	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (j)	(l)	(l)	2.70 (0.02 to 5.38)	MD 2.70 higher (0.02 higher to	Moderate

Quality assessment						Summary of findings				
								Effect		
Author(s)	Design	Limitations	Inconsistency	Indirectness	Imprecision	Early Supported Discharge Mean (SD)/ Median (range)/frequency (%)	Usual care Mean (SD)/ Median (range)/ Frequency (%)	Mean difference/ Median difference/ SMD/Risk Ratio (95% CI)	Absolute effect/ Mean Difference (MD) or Standardised Mean Difference (SMD) (95% CI) or P value	Confidence (in effect)
									5.38 higher)	
Global Nottingham Health Profile 2 (52 weeks follow-up) (Better indicated by higher values)										
Fjaeartoft, 2004[82]	RCT	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (j)	(l)	(l)	4.90 (-0.46 to 10.26)	MD 4.90 higher (-0.46 lower to 10.26 higher)	Moderate
Hospital Anxiety and Depression Scale – Anxiety (52 weeks follow-up) (Better indicated by lower values)										
Rudd, 1997[224]	RCT	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (i)	20/136 (14.7%)	7/126 (5.6%)	RR 2.65 (1.16 to 6.05)	92 more per 1000 (from 9 more to 281 more)	Low

Quality assessment						Summary of findings				
								Effect		
Author(s)	Design	Limitations	Inconsistency	Indirectness	Imprecision	Early Supported Discharge Mean (SD)/ Median (range)/frequency (%)	Usual care Mean (SD)/ Median (range)/ Frequency (%)	Mean difference/ Median difference/ SMD/Risk Ratio (95% CI)	Absolute effect/ Mean Difference (MD) or Standardised Mean Difference (SMD) (95% CI) or P value	Confidence (in effect)
Hospital Anxiety and Depression Scale – Depression (52 weeks follow-up) (Better indicated by lower values)										
Rudd, 1997[224]	RCT	Serious limitations(b)	No serious inconsistency	No serious indirectness	Very serious imprecision (e)	24/136 (17.6%)	21/126 (16.7%)	RR 1.06 (0.62 to 1.8)	10 more per 1000 (from 63 fewer to 133 more)	Very low
Caregiver Strain Index (6 weeks follow-up) (Better indicated by lower values)										
Askim, 2004[12]	RCT	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (j)	1.5 (2.3)	2.2 (2.4)	-0.70 (-1.91, 0.51)	MD 0.7 lower (1.91 lower to 0.51 higher)	Moderate
Caregiver Strain Index (24 & 26 weeks follow-up) (Better indicated by lower values)										
Anderson,	RCT	Serious	No serious	No serious	Serious	Anderson:	Anderson:	-0.03 (-0.26,	MD 0.03	Low

Quality assessment						Summary of findings				
								Effect		
Author(s)	Design	Limitations	Inconsistency	Indirectness	Imprecision	Early Supported Discharge Mean (SD)/ Median (range)/frequency (%)	Usual care Mean (SD)/ Median (range)/ Frequency (%)	Mean difference/ Median difference/ SMD/Risk Ratio (95% CI)	Absolute effect/ Mean Difference (MD) or Standardised Mean Difference (SMD) (95% CI) or P value	Confidence (in effect)
2000[10]; Askim, 2004[12]		limitations(c)	inconsistency	indirectness	imprecision (j)	0.2 (0.4); Askim: 1.0 (1.6)	0.2 (0.4); Askim: 1.8 (2.5)	0.20)	lower (0.26 lower to 0.20 higher)	
Caregiver Strain Index (52 week follow-up) (Better indicated by lower values)										
Askim, 2004[12]; Donnelly, 2004[69]; Fjaertoft, 2004[82]; Rudd, 1997[224]	RCT	Serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	Askim: 1.2 (1.9); Donnelly: 5.9 (2.9); Fjaertoft: 15.7 (2.7); Rudd: 5 (4)	Askim: 1.7 (2.7); Donnelly: 6 (4.2); Fjaertoft: 16.4 (3.1); Rudd: 4 (3)	-0.13 (-0.98, 0.72)	MD 0.13 lower (0.98 lower to 0.72 higher)	Moderate

[(a)] Blinding not done for outcome assessment.
[(b)] Blinding of outcome assessment not done for Rudd, 1997.
[(c)] Blinding not done for outcome assessment (Anderson, 2000).
[(d)] Confidence interval crossed one end of agreed MID.
[(e)] Confidence interval crossed both ends of the default MID.

[f] Imprecision could not be assessed because only odds ratio was reported.
[g] Relative and absolute effect could not be assessed because odds ratio was reported.
[h] Data as reported by the author(s).
[i] Confidence interval crossed one end of the default MID.
[j] Confidence interval crossed one end of default MID.
[k] Confidence interval crossed both ends of default MID.
[l] Mean difference reported. Generic Inverse Variance used.
[m] Imprecision could not be assessed because only median and interquartile values reported.
[n] Mean difference could not be assessed because median and interquartile values reported.
[o] Imprecision/ Relative and absolute effect could not be assessed because only the mean number of days was reported.

5.4.2.2 Economic evidence

Eight analyses were included that compared early supported discharge with usual care: one modelled cost-utility analysis[183] and seven cost-consequence analyses that reported an analysis of costs alongside clinical outcomes from a randomised clinical trial included in the clinical review[8,22,69,83,172,255,274]. These are summarised in the economic evidence profile below (**Table 19**). Further details on each study are available from the evidence tables in Appendix I. Three identified analyses comparing ESD with usual care were excluded for methodological reasons (Anderson 2002[9], Larsen 2006[146], Saka 2009[228]).

Table 19: Economic evidence profile: early supported discharge (ESD) versus usual care

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effect(a)	ICER	Uncertainty
Anderson 2000[8] (Australia)	Partially applicable (b)(c)(d)	Potentially serious limitations (g)(h)(l)	• Cost consequence analysis • Within-RCT analysis – RCT included in clinical review (Anderson 2000[10]) • Follow-up: 6 months	-£1217(m) (ESD cost saving)	From clinical review – Anderson 2000[10] • SF36 (MD): physical functioning -1.2 (-13.3, 10.9); social functioning -8,1 (-19.89, 3.69) • Barthel (MD): 0 (-2.0, 2.0) • Falls (RR): 0.75 (0.26, 2.17) • Caregiver strain (MD): 0.00 (-0.23, 0.23)	N/A	• Incremental cost CI: -£2306 to -£127(o) • DSA: hospital-based care became less costly than ESD when hospital costs were reduced by 50%
Beech 1999[22] (UK)	Partially applicable (b)(d)	Potentially serious limitations (g)(i)(h)(j)	• Cost consequence analysis • Within-RCT analysis – RCT included in clinical review (Rudd 1997[224])	-£632 (ESD cost saving)	From clinical review – Rudd 1997[224] • Mortality (RR): 0.75 (0.47, 1.19) • Barthel (SMD): 0.0 (-0.24, 0.24)	N/A	• Incremental cost CI: NR; p=NR • DSA: conclusions not impacted under plausible

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effect(a)	ICER	Uncertainty
			• Follow-up: 12 months.		• HADS (RR): 2.65 (1.16, 6.05) • Caregiver strain (SMD): 1.00 (-0.19, 2.19)		variations in length of stay and overhead rates
Donnelly 2004[69] (UK)	Partially applicable (e)(d)	Potentially serious Limitations (g)(i)(h)(l)	• Cost-consequences analysis • Within-RCT analysis – RCT included in clinical review (Donnelly 2004[69]). • Follow-up: 12 months	-£1578 (ESD cost saving)	See clinical review – Donnelly 2004[69] • Barthel 0-20: 0.24 (-0.16, 0.64) • Nottingham ADL (MD): 1.57 (-0.87, 4.01) • SF-36 (MD): physical functioning 0.92 (-11.71, 13.55); mental health 2.19 (-5.48, 9.86) • EuroQol VAS(e): -1.85 (-9.60, 5.90) • Caregiver strain (SMD): 0.03 (-0.52, 0.57)	N/A	• Incremental cost CI: -£12,115, £4851(o) • No SA
Fjaertoft 2005[83] (Norway)	Partially applicable (b)(c)(d)	Potentially serious limitations (g)(h)(l)	• Cost-consequence analysis • Within-RCT analysis – RCT included in clinical review (Indredavik 2000[121] and Fjaetoft 2004[82]) • Follow-up: 12 months	-£1491(m) (ESD cost saving)	From clinical review – Indredavik 2000[121] and Fjaetoft 2004[82] • Barthel (MD): 1.72 (1.10-2.70) • Mortality (RR): 0.87 (0.43, 1.76) • Caregiver strain index (SMD): 0.24 (-0.00, 0.49)	N/A	• Incremental cost CI: NR; p=0.127 • Stratification by functional impairment level: ESD not cost saving in the least severe group (£1477, CI NR, p=0.200) • DSA: varying costs did not impact conclusions
McNamee 1998[172] (UK)	Partially applicable (b)(d)	Potentially serious limitations (g)(i)(h)(j)	• Cost-consequence analysis • Within-RCT analysis – RCT included in clinical review (Rodgers 1997[219]) • Follow-up: 6 months	-£325 (ESD cost saving)	From clinical review – Rodgers 1997[219] • Mortality (RR): 0.25 (0.03, 2.15)	N/A	• Incremental cost CI: NR; p=NR • Stratification by functional impairment: ESD not cost saving in the least severe

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effect(a)	ICER	Uncertainty
							group (£2400, CI NR, p=0.001) • DSA: ESD not cost saving when the lower range of the cost of bed days was used (£578)
National Audit Office 2010[183] (NAO) (UK)	Partially applicable (f)	Potentially serious limitations (k)	• Cost–utility analysis • Discrete event simulation model • Time horizon: 10 years • Health states: severe, moderate and mild disability defined by Barthel score • Treatment effects (probability of being mild, moderate or severe) were determined at 1 year (data from Rudd et al 1997[224])	£804	0.13 QALYs	£6184 (n)	• Uncertainty around ICER not reported • DSA: conclusions not sensitive to discount rate or extent of coverage of ESD
Von Koch 2001[274] (Sweden)	Partially applicable (b)(c)(d)	Potentially serious limitations (g)(i)(h)(j)(l)	• Cost-consequences analysis • Within-RCT analysis – RCT included in clinical review (von Koch 2000, 2001[274,275] • Follow-up: 12 months	-£1333(m) (ESD cost saving)	From clinical review – von Koch 2000, 2001[274,275]. • Barthel ADL (MD): 2.75 (0.77, 9.77) • Falls (RR): 1.02 (0.72, 1.43)	N/A	• Incremental cost CI: NR; p=NR • No SA
Teng 2003[255] (Canada)	Partially applicable (b)(c)(d)	Potentially serious limitations (g)(h)(i)	• Cost-consequence analysis • Within-RCT analysis – based on RCT included in clinical review (Mayo 2000[170]) • Follow-up: 3 months	-£1695(m) (ESD cost saving)	From clinical review – Mayo 2000[170] • SF36 (MD): physical component 5.00 (0.82, 9.18); mental health -0.20 (-4.73, 4.33) • Barthel 0-100 (MD): 2.0 (-1.72,	N/A	• Incremental cost CI: NR; p=NR • DSA: conclusions not sensitive to varying overhead rate

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effect(a)	ICER	Uncertainty
					5.72)		

CI: confidence interval; DSA = deterministic sensitivity analysis; ICER = incremental cost effectiveness ratio; MD = mean difference; NR = not reported; RR = relative risk; SA = sensitivity analysis; SMD = standardised mean difference.

(a) For within-RCT cost-consequence analyses the health outcomes reported in clinical review are included in table as reported as part of clinical review.
(b) QALYs not used.
(c) Some uncertainty about applicability of non-UK resource use and unit costs.
(d) Some uncertainty about applicability of resource use and unit costs from over 10 years ago.
(e) EuroQol reported but unclear if EQ5D or visual analogue scale part of tool used. Assumed VAS as reports on scale 0-100.
(f) Discounting not in line with NICE methodological guidance.
(g) RCT-based analysis so from one study by definition therefore not reflecting all evidence in area.
(h) Some uncertainty about whether time horizon is sufficient.
(i) Some local costs used; some uncertainty as to whether these will reflect national costs.
(j) Doesn't report if residential care has been considered in analysis.
(k) Unclear how the health outcomes, health and social care costs of each health states were calculated. Not clear whether the study considered the costs of long-term care such as residential care (nursing homes and residential homes). Unit cost sources unclear.
(l) Limited/no sensitivity analysis.
(m) Converted to UK pounds using relevant purchasing power parities[194].
(n) ICER calculated by the NCGC health economist using the incremental costs of £804 and 0.13 QALYs. The actual NAO study reported an ICER of £2,881 but is unclear how this figure was obtained. The author of the report was contacted over this specific issue but no feedback was received at the time of writing.
(o) Total mean costs, difference in mean total costs and confidence interval for difference calculated by NCGC health economist by summing cost categories. Standard error of difference was calculated assuming independence of cost categories as covariance was not available; this is judged likely to underestimate uncertainty.

5.4.2.3 Evidence statements

Clinical evidence statements

One study[12] comprising 62 participants found no significant difference in the Barthel index at 6 and 26 follow-up between the Early Supported Discharge group and the usual care group (MODERATE CONFIDENCE IN EFFECT).

One study[170] comprising 114 participants found no significant difference in the Barthel index at 12 weeks follow-up between the Early Supported Discharge group and the usual care group (LOW CONFIDENCE IN EFFECT).

Three studies[12],[69],[224] comprising 506 participants found no significant difference in the Barthel index at 52 follow-up between the Early Supported Discharge group and the usual care group (LOW CONFIDENCE IN EFFECT).

Two studies[10],[275] comprising 169 participants found no significant difference in falls experienced in the Early Supported Discharge group compared to the usual care group at 24 and 52 weeks follow-up (VERY LOW CONFIDENCE IN EFFECT).

Three studies[12],[170],[224] comprising 507 participants found a significant difference in length of hospital stay at 52 weeks follow-up (measured by inpatient stay) in favour of the Early Supported Discharge group compared to the usual care group (MODERATE CONFIDENCE IN EFFECT).

One study[69] comprising 113 participants found no significant difference in length of hospital stay at 52 weeks follow-up between the Early Supported discharge group and the usual care group (VERY LOW CONFIDENCE IN EFFECT)

Six studies[10],[12],[20],[121],[219],[224] comprising 968 participants found no significant difference in mortality between the Early Supported Discharge group and the usual care at 12 to 52 weeks follow-up (LOW CONFIDENCE IN EFFECT)

One study[69] comprising 113 participants found no significant difference in the Nottingham ADL at 52 weeks follow-up between the Early Supported Discharge group and the usual care group (MODERATE CONFIDENCE IN EFFECT).

Three studies[10],[219], [275] comprising 356 participants found no significant difference in readmissions to hospital at 24 and 52 weeks follow-up between the Early Supported Discharge group and the usual care group (VERY LOW CONFIDENCE IN EFFECT).

One study[10] comprising 86 participants found no significant difference in the physical function of the SF-36 at 24 weeks follow-up between the Early Supported Discharge group and the usual care group (MODERATE CONFIDENCE IN EFFECT).

One study[10] comprising 86 participants found no significant difference in the social function of the SF-36 at 24 weeks follow-up between the Early Supported Discharge group and the usual care group (LOW CONFIDENCE IN EFFECT).

One study[170] comprising 114 participants found a significant difference in the physical health of the SF-36 at 12 weeks follow-up in favour of the Early Supported Discharge group compared to the usual care group (LOW CONFIDENCE IN EFFECT).

One study [170] comprising 114 participants found no significant difference in the mental health of the SF-36 at 12 weeks between the Early Supported Discharge group and the usual care group (MODERATE CONFIDENCE IN EFFECT).

One study[69] comprising 113 participants found no significant difference in physical health of the SF-36 at 52 weeks follow-up between the Early Supported Discharge group and the usual care group (HIGH CONFIDENCE IN EFFECT).

One study[69] comprising 113 participants found no significant difference in mental health of the SF-36 at 52 weeks follow-up between the Early Supported Discharge group and the usual care group (MODERATE CONFIDENCE IN EFFECT).

One study[69] comprising 113 participants found no significant difference in the EuroQol at 52 follow-up between the Early Supported Discharge group and the usual care group (HIGH CONFIDENCE IN EFFECT).

One study [82] comprising 320 participants found no significant difference in the Global Nottingham Health Profile 1 at 52 weeks between the Early Supported Discharge group and the usual care group (MODERATE CONFIDENCE IN EFFECT).

One study [82] comprising 320 participants found no significant difference in the Global Nottingham Health Profile 2 at 52 weeks between the Early Supported Discharge group and the usual care group (MODERATECONFIDENCE IN EFFECT).

One study[224] comprising 262 participants found that significantly less proportion of people in the usual care experienced anxiety at 52 weeks follow-up compared to the early supported discharge group (LOW CONFIDENCE IN EFFECT)

One study[224] comprising 262 participants found no significant difference in depression at 52 weeks follow-up between the early supported discharge group and the usual care group (VERY LOW CONFIDENCE IN EFFECT)

One study[12] comprising 62 participants found no significant difference in caregiver strain at 6 weeks follow-up between the Early Supported Discharge group and the usual care group (MODERATE CONFIDENCE IN EFFECT).

Two studies[10],[12] comprising 148 participants found no significant difference in caregiver strain at 24 and 26 weeks follow-up between the Early Supported Discharge group and the usual care group (LOW CONFIDENCE IN EFFECT).

Four studies[12],[69],[82],[224] comprising 826 participants found no significant difference in caregiver strain at 52 weeks follow-up between the Early Supported Discharge group and the usual care group (MODERATE CONFIDENCE IN EFFECT).

Economic evidence statements

A UK cost–utility model found ESD to be cost-effective compared to usual care (directly applicable, potentially serious limitation)[183].

Seven within-RCT cost-consequence analyses (partially applicable, potentially serious limitations) found costs with ESD to be similar or lower than usual care taking into account hospital and community costs with follow-up over 3-12 months[8,22,69,172,255,274]. These studies also generally found health outcomes to be equivalent or improved with ESD.

5.4.3 Recommendations and link to evidence

Recommendations	**8. Offer early supported discharge to people with stroke who are able to transfer from bed to chair independently or with assistance, as long as a safe and secure environment can be provided.**

	9. Early supported discharge should be part of a skilled stroke rehabilitation service and should consist of the same intensity of therapy and range of multidisciplinary skills available in hospital. It should not result in a delay in delivery of care. **10. Hospitals should have systems in place to ensure that:** • **people after stroke and their families and carers (as appropriate) are involved in planning for transfer of care, and carers receive training in care (for example, in moving and handling and helping with dressing)** • **people after stroke and their families and carers feel adequately informed, prepared and supported** • **GPs and other appropriate people are informed before transfer of care** • **an agreed health and social care plan is in place, and the person knows whom to contact if difficulties arise** • **appropriate equipment (including specialist seating and a wheelchair if needed) is in place at the person's residence, regardless of setting.**
Relative values of different outcomes	The review of the evidence included the following outcomes: disability, quality of life, and carer strain as well as falls, mortality and length of stay. There was concern that measures of disability used in the Barthel index were limited by the ceiling effect and that measures of quality of life did not capture the domains important to patients such as cognitive and communication difficulties. Definitions of the Barthel index classification given in the summary tables were taken from the paper by D Wade as agreed with the GDG [277]. The GDG noted that patients recruited to studies were on average in the mild to moderate range of the Barthel index (10-14 moderate, 15-19 mild) [10,12,20,69,121,170,219]. The GDG noted that the results shown in the mortality outcomes were difficult to interpret due to improvements in stroke care and mortality outcomes over the last few years which would not be reflected in the studies included in the analysis of evidence (studies ranged from 1997 to 2004).
Trade-off between clinical benefits and harms	The GDG stressed the importance of developing a consensus on what early supported discharge should comprise of, as this was variable at present. The GDG noted that early supported discharge services should be able to offer similar intensity and skill mix available in-hospital without a delay of delivery. The GDG also highlighted that this intervention could place a burden on the carer and noted the importance of the integration of health and social care to enable an adequate assessment including equipment needs and a care needs assessment undertaken and care plan agreed for the patient and their family. The GDG noted the importance of patients and their families having a point of contact if needed. Existing community rehabilitation teams should also be engaged in this process and the patient's GP kept fully informed.
Economic considerations	The GDG considered the evidence to suggest that ESD is cost effective compared to usual care. All of seven within-RCT analyses found that ESD was cost saving compared to usual care taking into account hospital and community costs (which often included social care costs) up to a year; they also found that it was at least as effective. A modelled cost-utility analysis

	found ESD to be cost-effective compared to usual care, with an incremental cost-effectiveness ratio well below the threshold adopted by NICE. The GDG agreed that, since the clinical evidence suggests that ESD is at least as effective as usual care, and since there is evidence that it is also likely to have lower costs, ESD represents a cost-effective intervention for stroke patients. The GDG noted that the main cost savings of ESD are linked to a potentially shorter length of hospital stay and that this also has the potential to free-up acute care hospital beds for other stroke patients. The GDG also noted that ESD programmes are already commonly implemented throughout the UK NHS for appropriate patients.
Quality of evidence	Three of the studies showed that Early Supported Discharge reduced length of stay in hospital[12,170,224]. The assessment of confidence in the results for this outcome was moderate. There did not appear to be any significant difference in outcomes that relate to disability, quality of life, or carer strain. Confidence in the results for other outcomes was limited due to the study design or to variations in how the results were reported. The GDG considered that anecdotally it would be expected that early supported discharge would put a greater burden on the carer but this was not shown in the studies by Askim and Anderson [10,12]. The GDG agreed with the findings of no difference between groups at one year[12,69,82,224].
Other considerations	The GDG noted that there was no adequate description of the composition of usual care or early supported discharge in the studies analysed. Therefore it was not possible to specify the components of ESD within the recommendation. Whilst this method of delivery would be suitable for many patients, the GDG agreed that it was not suitable for all and for some patients rehabilitation within a hospital setting would be more appropriate. This is reflected by the patients recruited into the trials who were less severely affected after their stroke. The GDG noted that often patients experience distress at the point of discharge, feeling services are disjointed and provision is inadequate. In order to address these concerns, consensus recommendations were made indicating the planning, supply of equipment and support for the patient and their carers that need to be provided by the multi-agencies involved in the delivery of care. ESD teams within the studies varied but included: specialist physiotherapists, occupational therapists, speech and language therapists, rehabilitation nurses, consultants in rehabilitation, dieticians and social workers. The group noted that the studies did not include clinical neuropsychology input and this may reflect practice at the time of the studies. The consensus of the group was that neuropsychology should be considered part of the rehabilitation team. The GDG thought it important that future studies recognise carer and patient perspectives and quality of life were important outcomes to be measured for both groups.

5.4.4 Transfer of care from hospital to community

5.4.5 Evidence Review: What planning and support should be undertaken by the multidisciplinary rehabilitation team before a person who had a stroke is discharged from hospital or transfers to another team/setting to ensure a successful transition of care?

Population	Adults and young people 16 or older who have had a stroke
Components	1. Discharge planning 2. Emotional / educational support 3. Co-ordination and resources of other services/agencies (such as social care)

Outcomes	4. Patient and carer satisfaction 5. Successful discharge 6. Quality of life 7. optimised strategies to minimise impairment and maximise activity/participation

5.4.6 Delphi statements where consensus was achieved

Table 20: Table of consensus statements, results and comments (percentage in the results column indicates the overall rate of responders who 'strongly agreed' with a statement and 'amount of comments' in the final column refers to rate of responders who used the open ended comments boxes, i.e. No. people commented / No. people who responded to the statement)

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
	Each patient should have a documented discharge report which has been discussed with the person who has had a stroke and their carer/s prior to transfer of care, including discharges to residential settings.	75.5	14/98 (14%) panel members commented This was seen as important, but it was questioned whether this would be different to the GP report, a copy of which would be given to the person who has had a stroke. This should be written in an accessible way.
	A discharge report (informing ongoing rehabilitation planning) should contain information about the following: Diagnosis and health status Mental capacity Functional abilities Transfers and mobility Care needs for washing, dressing, toileting and feeding Psychological and emotional needs Medication needs Social circumstances Management of risk including the needs of vulnerable adults Ongoing goals Ways of accessing rehabilitation services	 86.8 69.7 86.8 82.8 82.8 77.7 84.8 76.7 74.7 76.5 74.4	31/99 (31%) panel members commented A few further suggestions and comments were made: The individual's named point of contact. Joint health and social care plan. Stroke Association Information Further comments: The terms 'mental capacity' was queried – i.e. capacity for what, and whether 'cognitive status' may be a better term It was felt not necessary to have all these for all people.
	A home visit (with the person who has had a stroke present) may be required when simulation of the home environment set up in the inpatient setting has been inconclusive or there is an indication for further assessment.	69.8	14/96 (14%) panel members commented A limited number of panel members provided comments for this statement: One person felt that there were limits on staff time and resources

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
			Another person stated that this depended on whether an early supported discharge team was available. This could delay discharge from hospital was mentioned. The term 'may' was queried.
4.	Local systems with open communication channels and timely exchange of information should be established to ensure that the person who has had a stroke is able to transfer to their place of residence in a well-timed manner.	71.7	10/99 (10%) panel members commented Of the ten people who commented on this statement seven indicated that the phrasing of the statement was confusing and contained jargon. Of the other three, one commented on the role of the key worker, another person commented that this should minimise duplication and administration and the third person stated that this should be done as soon as it is safe to do so.
5.	Local health and social care providers should have established standard operating procedures to ensure a safe discharge process.	74.0	11/100 (11%) panel members commented Individual issues were raised in the comments: Any changes to procedures need to be communicated in timely fashion Take into account person's wishes and be aware of carer stress and vulnerable adult procedures Ideally joint standard procedures A need for flexibility and broad guidance that can be easily individualised, rather than prescriptive procedures.

5.4.7 Delphi statement where consensus was not reached

Number	Statement	Results %	Amount and content of panel comments – or themes
1.	An access visit (without the person present) can ascertain suitability of access to, from and within the property in respect to the person's functional, cognitive status and managing risk.	36.6	In round 2 - 20/98 (20%) panel members commented; 15/84(18%) in round 3 and 13/71 (18%) in round 4:

Number	Statement	Results %	Amount and content of panel comments – or themes
			The majority of comments expressed that the statement was **unspecific and did not say whether it should be done or in what circumstances** ("The issue is when – always, sometimes, why, how to decide."). Several people expressed the opinion that this statement was too obvious, since it included the word 'may' or later the word 'can'.
2.	A home visit can ascertain a person's potential for managing risk and cognitive/functional impairment within a familiar environment.	56.8	In round 2 - 11/99 (11%) panel members commented; 13/84(15%) in round 3 and 8/70 (11%) in round 4: The majority of comments expressed that the statement was **unspecific and did not say whether it should be done or in what circumstances**. ("…guidelines should be given guidance about to whom and under what circumstances a visit - either access or with the patient should be done." "usually not required if ESD team involved in care".) Several people expressed the opinion that this statement was too obvious, since it included the word 'may' or later the word 'can'.
3.	Both access and home visits should be coordinated by an occupational therapist and if this is not possible they should have clinical oversight from an occupational therapist.	19.4	In round 2 - 38/95 (40%) panel members commented; 34/83(41%) in round 3 and 15/72 (21%) in round 4:

Number	Statement	Results %	Amount and content of panel comments – or themes
			The main point of contention was **whether or not an OT** should oversee this. "although the OT would usually be involved, this does not need to be the case and it may be appropriate for another member of the team to co-ordinate/conduct this depending on what limitations the pt presented with."
4.	As part of rehabilitation care planning, both access and home visits can be used separately or sequentially, to ascertain suitability for rehabilitation, management of risk and management of life after stroke within the person's home environment.	52.1	In round 2 - 9/99 (9%) panel members commented; 9/83(11%) in round 3 and 11/71 (15%) in round 4: It was felt that this statement was **vague and did not define the circumstances of when and how** this should happen. There was also a comment that this **should not delay discharge** and that this is something the **community stroke team could undertake**.

5.4.8 Recommendations and links to Delphi consensus survey

Statements	9. Each patient should have a documented discharge report which has been discussed with the person who has had a stroke and their carer/s prior to transfer of care, including discharges to residential settings. 10. A discharge report (informing ongoing rehabilitation planning) should contain information about the following: • Diagnosis and health status • Mental capacity • Functional abilities • Transfers and mobility • Care needs for washing, dressing, toileting and feeding • Psychological and emotional needs • Medication needs

	• Social circumstances • Management of risk including the needs of vulnerable adults • Ongoing goals • Ways of accessing rehabilitation services 11. A home visit (with the person who has had a stroke present) may be required when simulation of the home environment set up in the inpatient setting has been inconclusive or there is an indication for further assessment. 12. Local systems with open communication channels and timely exchange of information should be established to ensure that the person who has had a stroke is able to transfer to their place of residence in a well-timed manner. 13. Local health and social care providers should have established standard operating procedures to ensure a safe discharge process.
Recommendations	**11. Before transfer from hospital to home or to a care setting, discuss and agree a health and social care plan with the person with stroke and their family or carer (as appropriate), and provide this to all relevant health and social care providers.** **12. Before transfer of care from hospital to home for people with stroke:** • **establish that they have a safe and enabling home environment, for example, check that appropriate equipment and adaptations have been provided and that carers are supported to facilitate independence, and** • **undertake a home visit with them unless their abilities and needs can be identified in other ways, for example, by demonstrating independence in all self-care activities, including meal preparation, while in the rehabilitation unit.** **13. On transfer of care from hospital to the community, provide information to all relevant health and social care professionals and the person with stroke. This should include:** • **a summary of rehabilitation progress and current goals** • **diagnosis and health status** • **functional abilities (including communication needs)** • **care needs, including washing, dressing, help with going to the toilet and eating** • **psychological (cognitive and emotional) needs** • **medication needs (including the person's ability to manage their prescribed medications and any support they need to do so)** • **social circumstances, including carers' needs** • **mental capacity regarding the transfer decision** • **management of risk, including the needs of vulnerable adults** • **plans for follow-up, rehabilitation and access to health and social care and voluntary sector services.**

	14. Ensure that people with stroke who are transferred from hospital to care homes receive assessment and treatment from stroke rehabilitation and social care services to the same standards as they would receive in their own homes. **15. Local health and social care providers should have standard operating procedures to ensure the safe transfer and long-term care of people after stroke, including those in care homes. This should include timely exchange of information between different providers using local protocols.** **16. After transfer of care from hospital, people with disabilities after stroke (including people in care homes) should be followed up within 72 hours by the specialist stroke rehabilitation team for assessment of patient-identified needs and the development of shared management plans.** **17. Provide advice on prescribed medications for people after stroke in line with recommendations in Medicines adherence (NICE clinical guideline 76).**
Economic considerations	No economic evidence was found on discharge of people after stroke. There are some costs associated with the assessment and follow-up visits (staff time and travel/transport cost); the GDG has considered the economic implications and concluded that in some circumstances the benefit of the intervention is likely to outweigh the costs.
Other considerations	Both the health and social care plan outlining requirements going forward as well as a summary of information on the admission and treatments given in hospital needs to be provided to appropriate people (including the GP) and the person who had the stroke. As part of the discharge documentation, a summary of rehabilitation activities would be included as usual practise. Having a local protocol drawn up between health and social care providers to ensure information is being relayed between both agencies prior to discharge is very important in ensuring a smooth discharge for the person and their families. It was noted that there is often a lack of information provided to families when the person is going to residential care. The GDG noted that it was very important that people who transfer from hospital to a care home should receive the same level of care and treatment as those who are able to return home. The GDG agreed that this was a neglected area and felt a consensus recommendation was warranted to initiate an improvement in current practice. Consensus was not reached regarding home visits through the modified Delphi. The GDG recognise that home visits are not required in all cases; however there are accepted situations where a home visit is indicated. Clinical indications for home visits being carried out may include the need to assess whether the person is able to mobilise around their own environment, and manage necessary transfers with or without equipment. Patients with cognitive or perceptual impairments may need

	to be assessed in their own environment to aid decision making regarding whether the patient is able to safely return home. Home visits or ward leave may be required to aid the patients' acceptance and transition back home with altered abilities following their stroke. When sufficient information (measurements, photographs) can be gained and 'mock up' can be achieved to fully assess a patient's ability in the hospital setting, visits may be unnecessary. There should be locally agreed situations where home visits would and wouldn't be conducted, and in what situations professions other than an Occupational therapist could conduct them. One such example may be a patient with minor equipment needs who is mobilising with one person on the ward may not require a home visit if they are being discharged with immediate ESD involvement. It is current practice that these are usually carried out by occupational therapists, but at times may be performed by other appropriate members of the MDT (for example physiotherapist), depending on the reason for the home visit, and would be overseen by an occupational therapist with knowledge of environmental risk assessment, equipment provision and adaptation. The GDG noted a large trial (HOVIS) which is soon to be published on this area. The need for a follow-up to be undertaken by the stroke rehabilitation team once the person had transferred to the community was viewed to be important to ensure management plans have been followed and to identify any further support. The GDG noted this was already documented in the Stroke Quality Standard and agreed this should be reinforced by a consensus recommendation following comments received by stakeholders.

6 Planning and delivering stroke rehabilitation

To ensure the safety of the person with stroke while maintaining a patient centred approach, key processes need to be in place. These processes include assessment on admission to the rehabilitation service, individualised goal setting and patient centred care-planning. This chapter reviews those processes.

A search for systematic reviews was carried out for assessment for rehabilitation, goal setting and rehabilitation planning. Direct evidence from systematic reviews was not identified for assessment for rehabilitation (6.1) and recommendations were therefore drawn from the modified Delphi consensus statement. A systematic review for goal setting (6.2) was identified and updated (Rosewilliam 2011 [221]). Not all aspects of goal setting were covered by the included systematic review and therefore additional Delphi statements were drafted from published national and international guidelines and recommendations were made based on both the review and the Delphi consensus statements. Direct evidence from systematic reviews was not identified for rehabilitation planning (section 6.3) and recommendations were therefore drawn from the modified Delphi consensus statement.

6.1 Screening and assessment

6.1.1 Evidence Review: In planning rehabilitation for a person after stroke what assessments and monitoring should be undertaken to optimise the best outcomes?

Population	Adults and young people 16 or older who have had a stroke
Components	• assessment • care plans • monitoring
Outcomes	• Patient and carer satisfaction • optimised strategies to minimise impairment and maximise activity/participation

6.1.2 Delphi statements where consensus was achieved

Table 21: Table of consensus statements, results and comments (percentage in the results column indicates the overall rate of responders who 'strongly agreed' with a statement and 'amount of comments' in the final column refers to rate of responders who used the open ended comments boxes, i.e. No. people commented / No. people who responded to the statement)

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
	After admission to hospital the person who has had a stroke should have the following assessed as soon as possible: • Positioning • Moving and handling • Swallowing • Transfers • Pressure area risk • Continence • Communication	 82.0 92.0 94.9 79.5 90.0 86.8	34/100 (34%) panel members commented: A number of **additional assessments/measurements** were suggested (a lot of these are covered in other sections): • Activities of daily living • Mood • Pain

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
	• Nutritional status	80.0 77.7	• Motor control • Cognition A number of people commented that the terminology '**sensory registration'** [the one option that did not reach consensus] was unclear.
1.	Comprehensive assessment takes into account: • Previous functional status • Impairment of psychological functioning • Impairment of physiological body functions and structures • Activity limitations due to stroke • Participation restrictions in life are stroke • Environmental factors (social physical and cultural)	 86.1 81.1 81.1 84.1 75.2 76.2	25/100 (25%) panel members commented: **Additional issues** to take into account: • Patient and carer views • Motivation • Co-morbidities
2.	Family members and/or carers should be informed of their rights for a carers' needs assessment.	71.7	11/99 (11%) panel members commented: This was generally viewed as an important issue. **Extracts**: 'Those carers who are passive need to be informed that this is available and many may be too timid to know they can request this assessment.'
3.	The impact of the stroke on the person's family, friends and/or carers should be considered and if appropriate they can be referred for support.	78.0	11/100 (13%) panel members commented: Comments were **divided**: • Some thought that this was obvious • Others thought that in reality there is a lack of available support mechanisms.
4.	People who have had a stroke should have a full neurological assessment including cognition, vision, hearing, power, sensation and balance.	69.0	19/84(23%) panel members commented: This was a statement that was added in Round 3 based on comments in Round 2. Comments to this statement were – more individual than in themes: • The **phrase 'full assessment** '

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
			was queried by one ("If you mean that a full neurological assessment includes a screening process that can lead to a more detailed assessment as needed then I 'strongly agree'") • Some people wanted **additional assessments** (swallow, coordination, movement control, shoulder subluxation for instance) • It was mentioned that this should be done **according to need** and that people should not be over assessed. • The need to have a **neurologist** doing this was questioned.
5.	Delphi panel members agreed with screening for the following: • Mood • Pain	69.8 68.6	In round 2 this was an open text question and 83 people answered; in round 3 this was rephrased into a statement with multiple options format and 18/83 (22%) commented: There was **confusion about some of the option**s and **additional screening tools** were suggested: • Dysphagia / Swallow tests • Falls • Carers Strain Index
6.	Routine collection and analysis of a range of measures should include: • National Institute of Health Stroke Scale • Barthel Index • Hospital Anxiety Depression Scale (HADS)	74.0 (of 50) selected as first option 46.5 (of 43) - as second option 56.3 (of 32) as third option	In round 2 - 40/87 (46%) panel members commented; 26/77(34%) in round 3. This was included in a different format in Round 3 (to select the three main). Those that did not reach consensus were: • Modified Rankin • Berg Balance Scale • EQ5D • General Health Questionnaire (GHQ) • Geriatric Depression Scale Some people **disliked** the fact that only **3 options** could be selected and stated that it depends on the individual patients which measures

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
			would be selected. Others panel members highlighted that **measures depend on the stage of rehabilitation** ("NIHSS is a reasonable baseline whereas the Berg is most useful beyond the acute phase. It also depends on what sort of 'analysis' you are expecting to be done. Is the data for understanding the severity of stroke or the outcome of rehab?") It was questioned whether the statement refers to **outcome or baseline measures** ("…It depends what you are trying to show? If it's outcomes and service demands? Maybe rehabilitation complexity scales to show the demands and resources you need. FIM to show functional outcomes perhaps instead of Barthel."). **Additional measures** were also suggested: • TOM • PHQ • Nottingham Extended Activities of Daily Living Scale

6.1.3 Delphi statement where consensus was not reached

Table 22: Table of 'non-consensus' statements with qualitative themes of panel comments

Number	Statement	Results %	Amount and content of panel comments – or themes
1.	The specific list of professional screening tools to be included: • Montreal Cognitive Assessment (MOCA) • Frenchay Aphasia Screening Test (FAST) • Malnutrition Universal Screening Tool (MUST) • The Waterlow Pressure score risk assessment tool (pressure ulcers)	25.4 22.5 42.6 44.9	In round 2 - 48/93 (52%) panel members commented; 40/72(56%) in round 3 – the options changed between rounds 2 and 3: A number of **additional scales/tools** were mentioned [some of which were already included in other statements]: • Berg Balance scale • Modified Rivermead Mobility Index • Mood

Number	Statement	Results %	Amount and content of panel comments – or themes
			• Therapy outcome measure • Screen for malnutrition **Validity, reliability and training** need to be taken into consideration. ("You should state 'using a recognised tool;" "The tool is not important so long as it is a validated tool. There is no need to direct which tools people should use.") **Concern** was raised about possible recommendations being **too prescriptive** ("These tools should only be suggested tools not prescriptive as the clinician should be able to make the decision as to the most appropriate tool". "The tool is not important as long as it is a validated tool. There is no need to direct which tools people should use".) Whether these were **screening tools** or **outcome measures** was also questioned.
2.	Data collection should be overseen by a national body.	62.0	In round 2 - 27/97 (28%) panel members commented; 21/81(26%) in round 3 and 16/71 (23%) in round 4: It was highlighted that this is **already in existence** in some place (such as the RCP audit, the Scottish Stroke Care Audit or the National Sentinel Stroke Audit)

6.1.4 Recommendations and links to Delphi consensus survey

Statements	14. After admission to hospital the person who has had a stroke should have the following assessed as soon as possible: • Positioning • Moving and handling • Swallowing • Transfers • Pressure area risk • Continence • Communication • Nutritional status

	15. Comprehensive assessment takes into account: • Previous functional status • Impairment of psychological functioning • Impairment of physiological body functions and structures • Activity limitations due to stroke • Participation restrictions in life are stroke • Environmental factors (social physical and cultural) 16. Family members and/or carers should be informed of their rights for a carers' needs assessment. 17. The impact of the stroke on the person's family, friends and/or carers should be considered and if appropriate they can be referred for support. 18. People who have had a stroke should have a full neurological assessment including cognition, vision, hearing, power, sensation and balance. 19. Delphi panel members agreed with screening for the following: • Mood • Pain 20. Routine collection and analysis of a range of measures should include: • National Institute of Health Stroke Scale • Barthel Index • Hospital Anxiety Depression Scale (HADS)
Recommendations	**18. On admission to hospital, to ensure the immediate safety and comfort of the person with stroke, screen them for the following and, if problems are identified, start management as soon as possible:** • **orientation** • **positioning, moving and handling** • **swallowing** • **transfers (for example, from bed to chair)** • **pressure area risk** • **continence** • **communication, including the ability to understand and follow instructions and to convey needs and wishes** • **nutritional status and hydration (follow the recommendations in Stroke [NICE clinical guideline 68] and Nutrition support in adults [NICE clinical guideline 32]).** **19. Perform a full medical assessment of the person with stroke, including cognition (attention, memory, spatial awareness, apraxia, perception), vision, hearing, tone, strength, sensation and balance.** **20. A comprehensive assessment of a person with stroke should take into account:** • **their previous functional abilities**

	• **impairment of psychological functioning (cognitive, emotional and communication)** • **impairment of body functions, including pain** • **activity limitations and participation restrictions** • **environmental factors (social, physical and cultural).** **21. Information collected routinely from people with stroke using valid, reliable and responsive tools should include the following on admission and discharge:** • **National Institutes of Health Stroke Scale** • **Barthel Index.** **22. Information collected from people with stroke using valid, reliable and responsive tools should be fed back to the multidisciplinary team regularly.** **23. Take into consideration the impact of the stroke on the person's family, friends and/or carers and, if appropriate, identify sources of support.** **24. Inform the family members and carers of people with stroke about their right to have a carer's needs assessment.**
Economic considerations	There are some costs associated with the screening and further assessment; the GDG has considered the economic implications and concluded that these interventions will improve the safety and quality of life of the person with stroke; the improvement in quality of life was considered likely to outweigh the costs.
Other considerations	The GDG agreed that in this context screening is a brief evaluation which allows the patient to be triaged and immediate management to be put in place to ensure the person's safety. Where there is evidence of functional impairments, more detailed assessment will then need to take place. Other assessments should be undertaken where there are specific needs of the patients. It was felt that assessing for mood was important and this was not made explicit in the survey and should be added into the recommendation. The GDG recognised that signs of impairments in psychological functioning (including mood) might not be directly apparent to the person who has had the stroke and the clinicians on admission to hospital at the time of screening. Therefore it was felt that these processes should be comprehensively assessed at a later stage. It was also agreed that in addition to limitations on activity, an assessment of participation restrictions should also be undertaken. The anxiety that neurological assessment implied that a neurologist would have to undertake the assessment was recognised by

	substituting the word 'medical'. The GDG felt a medical assessment was an integral part of a comprehensive rehabilitation assessment. Activity limitations as defined by the ICF include social attitudes, architectural characteristics, legal and social structures, as well as climate, and terrain. The GDG recognised that a range of additional measures to the Barthel, and National Institute of Health Stroke Scale may be used. Such measures should be used to compare cohorts of data, not to monitor individual progress for rehabilitation. Since none of the specific screening tools reached consensus the GDG were unable to make a recommendation. However, based on comments of the non-consensus statements the GDG recognised that if measures were to be collected they should be standardised measurement tools with psychometrically robust properties, and staff should be trained in their use and findings should be fed back to the team. The GDG recognised that there is a distinction between measures and screening tools that should not be used as outcomes. Opinion on support for family and carers was divided in the survey, with some thinking this would always be done and others that in reality there is a lack of organised mechanisms to provide support. The GDG noted that it would be usual to refer the person to their GP if it was felt they needed to be referred for additional support. The MDT stroke team would provide information on where support could be found.

6.2 Setting goals for rehabilitation

6.2.1 Evidence Review: Does the application of patient goal setting as part of planning stroke rehabilitation activities lead to an improvement in psychological wellbeing, functioning and activity?

Clinical Methodological Introduction	
Population	Adults and young people 16 or older who have had a stroke.
Intervention	Any patient goal setting approach
Comparison	Alternative rehabilitation goal setting approaches
Outcomes	• Psychological measures and health related quality of life • Physical function • Activities of Daily Living (ADL) These may include: Barthel, Nottingham extended activities of daily living, FIM, rating scales, survey data (quantitative), themes identified by qualitative studies

6.2.1.1 Clinical Evidence Review

A search was conducted for systematic reviews comparing the clinical effectiveness of any patient goal setting approaches to alternative rehabilitation goal setting approaches to improve psychological wellbeing, function and activity in adults and young people 16 or older who have had a stroke.

One systematic review (Rosewilliam 2011 [221]) matching our protocol was identified. This review included twenty seven studies (eighteen qualitative, eight quantitative and one mixed method study). We included twenty one studies from this review matching our protocol. The systematic review explored the nature, extent and effects of applying patient-centred goal setting in stroke rehabilitation practice.

A further systematic search (using the same search terms as provided in the identified systematic review) was conducted for studies published since June 2010 which was the search cut-off date of the included systematic review. Two studies (Hale 2010 [100]; Worrall 2011 [287]) (**Table 23**) matching our protocol were identified from this update search and were also included for this review.

Table 23: Overview of the two additional studies from the top-up search since the systematic review search cut-off date. See Appendix H for extraction

Studies	Population/setting	Aims	Review methods
Hale 2010 [100]	4 community-based physiotherapist and seven stroke patients (three men, four women)	To explore the feasibility and acceptability of using *Goal Attainment Scaling (GAS) in home-based stroke rehabilitation (HBSR)	Qualitative descriptive study involving semi-structured in-depth interviews
Worrall 2011 [287]	50 participants with aphasia post stroke. All participants had to be able to participate in an in-depth interview in English using speech, gesture, writing, pictures, and/or drawings.	To describe the goals of people with aphasia and to code the goals according to the International Classification of Functioning, Disability and Health (ICF) (WHO, 2001)	Qualitative descriptive study involving semi-structured, in-depth interviews

*A standardised way of scoring the extent to which patient's individual goals is achieved in the course of intervention.

In the included systematic review (Rosewilliam 2011 [221]) the following methodology was adopted:

- Both qualitative (**Table 24**) and quantitative (**Table 25**) study designs were included in the review
- Quality of included studies were assessed by using quality criteria adapted from published literatures [256]; [106]; [184]. Different sets of quality criteria were used for the qualitative and quantitative studies
- Study quality assessment was done initially by one researcher and cross-checked by one of the two other authors
- Themes from all qualitative studies matching the review questions were pooled
- Findings were synthesized by aggregating the themes from the qualitative studies and relating them to findings from quantitative studies
- Data from the quantitative studies could not be meta-analysed due to lack of randomised trials
- Effect sizes (for included quantitative studies) were calculated where possible

For this review, we have added quality ratings (our confidence in the studies) to the qualitative and quantitative studies included in the systematic review. The quality ratings were based on quality characteristics (reported in the included systematic review) that were assessed in the review.

Studies from the systematic review were excluded if they addressed mixed neurological populations, if the proportion of patients with stroke is < 50% or if the number of stroke participants is unclear

For the additional qualitative studies identified in our update search:

- The study qualities of Hale 2010[100] and Worrall 2011[287] were assessed and rated using the quality criteria adapted from the included systematic review (**Table 26**)
- We merged findings from the themes that Hale 2010[100] identified: enthusiastically cautious, a tool in the box of interventions, time consuming, not easy to set goals. Findings within these themes matching the qualitative themes in the systematic review are presented (**in bold**) in our summary of findings table (**Table 27**)
- It was not possible to merge findings from Worrall 2011[287] as this study was strictly on aphasic stroke patients describing their goals and how these goals can be coded (by clinicians) according to the International Classification of Functioning, Disability and Health (ICF) (WHO, 2001). We therefore reported this study separately

Table 24: Qualitative studies in the included systematic review (Rosewilliam 2011 [221])

Study	Stroke samples/settings	Data collection	*Quality characteristics assessed	Confidence (in study)
Alaszewski 2004 [5]	Stroke patients, professionals from stroke rehabilitation services	Semi structured interviews	1,2,3,4,5,6,7,8,9,12,13,14	Moderate
Andreassen and Wyller 2005 [11]	Stroke patients not specified	Semi structured interviews	1,2,3,4,6,8,9,11,12,13,14	Moderate
Bendz 2003 [23]	Stroke unit	Open interviews with patients and notes from professionals	2,3,4,8,9,11,12,13,14	Moderate
Boutin-Lester and Gibson 2002 [28]	Stroke patients	Unstructured interviews by phone and in person	1,2,3,5,7,8,9	Very low
Cott 2004 [49]	Stroke patients, occupational therapist, neurological rehabilitation unit	Focus groups used to collect data	1,2,3,4,5,6,8,9,11,12,13,14	Moderate
Daniels 2002 [55]	Occupational therapists	Focus groups and case notes	1,2,3,4,5,6,7,8,9,10,11,12,13,14	High
Foye 2002 [85]	Occupational therapists	Surveys to describe ethically difficult situations in own words	1,2,3,4,6,7,8,9,11,12,13,14	Moderate

Study	Stroke samples/settings	Data collection	*Quality characteristics assessed	Confidence (in study)
Hale and Piggot 2005 [101]	Stroke physiotherapist	Semi structured interviews	1,2,3,4,5,6,8,9,10,11,12,13,14	Moderate
Lawler 1999 [149]	Stroke patients, carers and specialist nurses	Semi structured interviews	1,2,3,4,5,8,9,10,11,14	Low
Leach 2010 [150]	Professionals from stroke rehabilitation services	Semi structured interview	1,2,3,4,6,7,8,9,10,11,12,13,14	Moderate
McGrath and Adams 1999 [171]	Stroke patients	Structured interviews	1,2,4,6	Very low
Parry 2004 [200]	Stroke inpatient rehabilitation	Video records were analysed using conversational analysis	1,2,3,4,5,6,8,9,11,12,13,14	Moderate
Suddick and De souza 2006 [252]	Stroke units	Semi structured interview	1,2,3,4,5,6,8,9	Low
Timmermans 2009 [259]	Stroke patients	Semi structured interview	1,2,3,4,5,6,9,11,12,13,14	Moderate
Wressle 1999 [290]	Stroke patients, carer, professional and clinicians	Interviews and daily records	1,2,3,4,6,9	Low

*Quality characteristics assessed: 1. Clear aims 2. Adequate background 3. Appropriate methodology 4. Appropriate design 5. Appropriate recruitment strategy (sample and sampling) Appropriate data collection 6. Reliability of data collection tool 7. Validity of data collection tool 8. Data collection methods described adequately 9. Data analysis methods described adequately 10. Reflexivity 11. Ethical issues 12. Rigorous data analysis 13. Clear findings 14. Value of research

Table 25: Quantitative studies in the included systematic review (Rosewilliam 2011 [221])

Study	Participants and sample size	Design	Intervention used (if present)	*Quality characteristics assessed	Confidence (in study)
Combs 2010 [46]		case series design	Use of Canadian Occupational Performance Measure (COPM) to explore goals	1,5,6,9,10,11	Very low
Gilbertson 2000 [91]	138 stroke patients	Single blind randomized control trial	Client centred occupational therapy tailored to patient goals	1,2,3,4,9,10,11,13	Low
Monaghan 2005 [175]	75 stroke patients	Serial comparison design	A – Standard meeting form B – New form to enhance documentation	1,2,3,4,5,6,7,8,11,12	Moderate

Study	Participants and sample size	Design	Intervention used (if present)	*Quality characteristics assessed	Confidence (in study)
			of patient needs goals and involvement C – Above form and weekly ward rounds with patients, carers and doctors		
Phipps and Richardson 2007 [205]	CVA patients= 117	Retrospective analysis of records	Use of Canadian Occupational Performance Measure (COPM) to explore goals	1,3,4,8,9,10,11, 13	Low
Roberts 2005 [214]	9 stroke patients	pre and post intervention design	Use of Canadian Occupational Performance Measure (COPM) to explore goals	1,2,4,5,6,9,11,12,13,14	Low
Timmermans 2009** [259]	40 stroke patents	Cross sectional survey using semi structured interviews	-	1,2,9,11,13	Very low
Wressle 2002 [289]	206 stroke patients	Experimental design	Use of Canadian Occupational Performance Measure (COPM) to explore goals	1,3,6,9,11	Very low

*Quality characteristics assessed 1. Clearly focussed question 2. Appropriate design 3. Appropriate sample size 4. Lack of selection bias 5. Lack of performance bias 6. Appropriate intervention 7. Lack of observer bias 8. Lack of Hawthorne effect 9. Reliability of measures 10. Validity of measures 11. Appropriate statistics 12. Lack of confounding factors 13. Accurate results

**Timmermans 2009: a cross sectional survey using semi-structured format requiring quantitative and qualitative data (mixed methodology)

Table 26: Additional qualitative studies from the update search since search cut-off date of included systematic review – here with quality characteristics and ratings

Study	Stroke samples/settings	Data collection	Quality characteristics assessed	Confidence (in study)
Hale 2010 [100]	4 community-based physiotherapist and seven stroke patients	semi-structured in-depth interviews; detailed clinical case notes and researcher	1,6, 7, 8, 12, 13	Low

Study	Stroke samples/settings	Data collection	Quality characteristics assessed	Confidence (in study)
		field notes		
Worrall 2011 [287]	50 participants with aphasia post stroke	Qualitative descriptive study involving semi-structured, in-depth interviews	1,2,3,4,5,6,7,8,9,11,12,13,14	High

*Quality characteristics assessed: 1. Clear aims 2. Adequate background 3. Appropriate methodology 4. Appropriate design 5. Appropriate recruitment strategy (sample and sampling) Appropriate data collection 6. Reliability of data collection tool 7. Validity of data collection tool 8. Data collection methods described adequately 9. Data analysis methods described adequately 10. Reflexivity 11. Ethical issues 12. Rigorous data analysis 13. Clear findings 14. Value of research

Table 27: Summary of findings from the qualitative themes and quantitative evidence from systematic review (Rosewilliam 2011) [221] and additional qualitative study (Hale 2010) [100] from update search

QUALITATIVE THEMES	QUALITATIVE AND QUANTITATIVE FINDINGS	MATCHING QUALITATIVE AND QUANTITATIVE EVIDENCE
Perceptions of patients regarding person-centeredness in goal setting and factors influencing it	• Patients perceived that making progress towards personally meaningful goals had been good for their self-image and helped as a coping mechanism [171] (VERY LOW CONFIDENCE IN STUDY) • Other reasons cited are to get back to work, independence, not to be a burden to others and to avoid embarrassment in public [259] (VERY LOW CONFIDENCE IN STUDY) • Patients perceived that they were not in control of their goals and their involvement with goal setting was passive [295] (MODERATE CONFIDENCE IN STUDY) • Passivity was attributed to: – Limited access to information [49] (MODERATE CONFIDENCE IN STUDY) – Inability to accept their condition especially in the early stages of stroke [49] (MODERATE CONFIDENCE IN STUDY) • Participation in goal setting could be improved by processes such as formal documentation of the patient's views, empowering key workers to be proactive, responding flexibly to their changing needs and the use of grading systems to measure their goal achievement [295] [49] (MODERATE CONFIDENCE IN STUDIES) • Evidence suggest the use of explicit methods to improve patients' perception of active participation in goal setting practice [289] (VERY LOW CONFIDENCE IN STUDY)	Quantitative evidence: Maitra and Erway 2006 [164]; Wressle 2002 [289]; Timmermans 2009 [259] Qualitative evidence: Cott 2004 [49]; Bendz 2003 [23]; Andreassen 2005 [11]; McGrath 1999 [171]; Young 2008 [295];
Professionals' perceptions concerning person-centeredness in goal setting	• Patients' social and occupational needs were not explicitly incorporated into the treatment goals, thereby reflecting a perceptual practice gap [150] (MODERATE CONFIDENCE IN STUDY) • Patient-centeredness in goal setting would improve patient's	Qualitative evidence: Leach 2010 [150]; Daniels 2002 [55]; Hale 2010 [100]

QUALITATIVE THEMES	QUALITATIVE AND QUANTITATIVE FINDINGS	MATCHING QUALITATIVE AND QUANTITATIVE EVIDENCE
	motivation, effective use of time and contribute to holistic planning [150] (MODERATE CONFIDENCE IN STUDY) • Professionals ascribed reasons that could limit adoption of a patient-centred approach such as concerns about future risks, socio-cultural barriers, environmental and resource implications [150 55] (MODERATE TO HIGH CONFIDENCE IN STUDIES) • ***Set goals might be used as a means of encouraging, motivating and prompting patient [100] (LOW CONFIDENCE IN STUDIES)** • ***A measurement tool (GAS) was found useful in guiding treatment and assisting therapists to set patient-centred goals [100] (LOW CONFIDENCE IN STUDY)** • ***Professionals were concerned about the reliability of Goal Attainment Scaling (GAS) in that different therapists could set different indicators for the same patient [100] (LOW CONFIDENCE IN STUDY)**	
Status of patient-centeredness in current stroke rehabilitation goal setting practices	• Evidence suggests that current goal-setting practice is not largely patient-centred [150] (MODERATE CONFIDENCE IN STUDIES) • ***Indecision by professionals about the use of GAS in their practice [100] (LOW CONFIDENCE IN STUDY)**	Qualitative evidence: Leach 2010 [150]; Hale 2010 [100]
Consequences of discrepancies in perceptions and practice of goal setting process	• The review revealed discrepancies between patient and professional in their perceptions regarding level of patient involvement in the goal-setting process and also with regard to recovery and focus of rehabilitation [164] (LOW CONFIDENCE IN STUDY) • These discrepancies in perception of illness and recovery between the patient and professional lead to conflicts not just in the goal-setting process but also impacted on other realms of rehabilitation such as its delivery and the therapeutic relationship [150 28 101 5] (VERY LOW to MODERATE CONFIDENCE IN STUDIES)	Quantitative evidence: Maitra and Erway 2006 [164]; Qualitative evidence: Leach 2010 [150]; Boutin-Lester 2002 [28]; Alaszewski 2004 [5]; Hale 2005 [101]

QUALITATIVE THEMES	QUALITATIVE AND QUANTITATIVE FINDINGS	MATCHING QUALITATIVE AND QUANTITATIVE EVIDENCE
Ethical conflict	• Conflict arising due to a mismatch in values and priorities was highlighted as an important dilemma encountered in practice [85] (MODERATE CONFIDENCE IN STUDY)	No quantitative evaluation Qualitative evidence: Foye 2002 [85]
Challenges to patient participation in goal setting	• Inhibitory factors such as limited time, presiding professional routines and the single opportunity to meet clinicians post discharge for secondary risk management [150 252 200] (LOW to MODERATE CONFIDENCE IN STUDIES) • Patients participation in goal-setting was hindered by psychosocial factors such inability to accept the occurrence of stroke, depression, patients guarding against exposing their incompetence [150 49 200] (VERY LOW to MODERATE CONFIDENCE IN STUDIES) • Standard goal setting meeting which is held away from the patient and with standard documentation is not conducive to patient-centred goal setting [175] (MODERATE CONFIDENCE IN STUDY) • The factor mentioned by both professionals and patients was the stroke pathology with its highly unpredictable recovery prognosis and its effects, such as aphasia [150 149] (LOW and MODERATE CONFIDENCE IN STUDIES) • ***Setting goals and indicators could be time consuming especially with patients with severe impairment (for example, cognitive impairment) [100] (LOW CONFIDENCE IN STUDY)**	Quantitative evidence: Monaghan 2005 [175] Qualitative evidence: Leach 2010 [150]; Suddick 2006 [252]; Parry 2004 [200]; Cott 2004 [49]; Lawler 1999 [149]; Hale 2010 [100]
Strategies to develop person-centeredness in goal-setting practices	• A multidisciplinary team approach involving the patient along with specialists such as speech pathologists improves discussion and documentation of patient goals [150 175] (MODERATE CONFIDENCE IN STUDY) • Set patient-centred goals and then training, either conventional or innovative, tailored to those goals led to short-term improvement in activities of daily living, better global outcome, better motor outcomes and better self-perceived performance and satisfaction [214 205 46 91] (VERY	Quantitative evidence: Monaghan 2005 [175] ; Wressle 2002 [289]; Roberts 2005 [214]; Phipps 2007 [205]; Combs 2010 [46]; Gilbertson 2000 [91] Qualitative evidence: Leach 2010 [150]; Hale 2005 [101]; Daniels 2002 [55]; Cott 2004 [49]; Lawler 1999 [149]

QUALITATIVE THEMES	QUALITATIVE AND QUANTITATIVE FINDINGS	MATCHING QUALITATIVE AND QUANTITATIVE EVIDENCE
	LOW to LOW CONFIDENCE IN STUDIES) • Patient and family education regarding the pathology, process of rehabilitation and goal setting [150] (MODERATE CONFIDENCE IN STUDY) • Encouraging patients to identify goals that are in line with their expectation [150] (MODERATE CONFIDENCE IN STUDY) • Active decision making involving patients needed to be pitched to their participating ability (graded decision making) [49 55] (MODERATE to HIGH CONFIDENCE IN STUDIES) • The use standard measures to identify client-centred goals improved opportunity for patient participation in goal setting, their perception regarding participation and ability to recall their goals [149 289 214 205 46] (VERY LOW to LOW CONFIDENCE IN STUDIES)	

***Findings from additional qualitative study (Hale 2010) merged here with findings from included systematic review**

Additional qualitative study from update search since search cut-off date of included systematic review

Summary of findings:

Worrall 2011 [287] (HIGH CONFIDENCE IN EVIDENCE from this study): Describing the goals of people with aphasia and to code the goals according to the ICF

Return to pre-stroke life:

- Participants expressed their desire to be normal again and to escape their current situation and return home to the security of their old life

Communication:

- Participants with aphasia spoke of the importance of recovering their communicative function (for example, communication for basic needs as well as communication to express their opinions). They described intense feelings of frustration, hopelessness, isolation, and depression at not being able to talk
- Many stressed that the aphasia was of higher priority to them than their physical impairments
- Participants spoke of the need for communication rehabilitation to be connected to real life and about how communication gave them confidence

Information:

- Participants wanted more information about aphasia, stroke, prognosis, and what to expect at different stages of rehabilitation
- Having information allowed people to start taking control and to participate in decisions about their own therapy and their own rehabilitation

Speech therapy and other health services:

- Participants wanted speech therapy that met their needs at different stages of recovery, was relevant to their life, more frequent and continued for longer.
- Participants wanted positive relationships and interactions with their speech therapists and other health service providers

Control and independence:

- Some expressed frustration at not being a part of the decision making in their care, seeking information from sources other than health professionals

Dignity and respect:

- Many people reported a feeling of being disempowered by their aphasia. They wanted respect, stating that they were competent people, despite their communication difficulties.

Social, leisure, and work:

- To be able to carry out social activities and to feel comfortable in a crowd
- Younger people with aphasia were particularly aware of the loss of work and career and often held deep, strong desires to return to some employment

6.2.2 Economic evidence summary

Literature review

No relevant economic evaluations were identified.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs.

Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

Based on the details of the clinical studies, the resources associated with the goal setting intervention are equivalent to an hour of multi-disciplinary team time for the initial goal setting and half an hour for each review. These costs are summarised in **Table 28**.

Table 28: Intervention costs – goal setting

Resources	Frequency	Unit costs[(a)]	Cost per patient
Goal setting with multi-disciplinary team	1 hour	£136 per hour – psychologist £35 per hour – nurse £45 per hour – physiotherapist £45 per hour – occupational therapist £132 per hour – medical consultant	£393
Review of goal setting with multi-disciplinary team	30 minutes	£136 per hour – psychologist £35 per hour – nurse £45 per hour – physiotherapist £45 per hour – occupational therapist £132 per hour – medical consultant	£197

a) Estimated based on data and methods from Personal Social Services Research Unit 'Unit costs of health and social care' report and the following Agenda for Change salary bands- psychologist (band 8), physiotherapist and occupational therapist (band 6), nurse (band 5)[51] (typical salary bands identified by clinical GDG members).

6.2.3 Evidence statements

Clinical Evidence statements

Perceptions of patients regarding person-centeredness in goal setting and factors influencing it

Two studies [171] [259] found that patients perceived that making progress towards personally meaningful goals had been good for their self-image, getting back to work, independence, avoiding embarrassment in public and helped as a coping mechanism (MODERATE CONFIDENCE IN STUDIES)

One study [49] found that patients perceived they were not in control of their goals and their involvement with goal setting was passive (MODERATE CONFIDENCE IN STUDY)

Two studies [295] [49] found that participation in goal setting could be improved by processes such as formal documentation of the patient's views, empowering key workers to be proactive, responding flexibly to their changing needs and the use of grading systems to measure their goal achievement (MODERATE CONFIDENCE IN STUDIES)

Professionals' perceptions concerning person-centeredness in goal setting

One study [150] found that patients' social and occupational needs were not incorporated into the treatment goals, and that patient-centeredness in goal setting would improve patient's motivation, effective use of time and contribute to holistic planning (MODERATE CONFIDENCE IN STUDY)

Two studies [150] [55] highlighted 'concerns about future risks', socio-cultural barriers, environmental and resource implications as reasons that could limit adoption of a patient-centred approach in goal setting (MODERATE to HIGH CONFIDENCE IN STUDIES)

One study [100] found that a measurement tool (GAS) was found useful in guiding treatment and assisting therapists to set patient-centred goals but concerns were raised about the reliability of this tool (LOW CONFIDENCE IN STUDY)

Status of patient-centeredness in current stroke rehabilitation goal setting practices

One study [150] found that current goal-setting practice is not largely patient-centred (MODERATE CONFIDENCE IN STUDY)

One study [100] found that professionals (physiotherapist) were undecided about the use of Goal Attainment Scaling (GAS) in their practice (LOW CONFIDENCE IN STUDY)

Consequences of discrepancies in perceptions and practice of goal setting process

Four studies[150 28,101 5] found that discrepancies in perception of illness and recovery between the patient and professional lead to conflicts in the goal-setting process which also impacted on other realms of rehabilitation (VERY LOW to MODERATE CONFIDENCE IN STUDIES)

Challenges to patient participation in goal setting

Five studies [149 150 252 200 175] highlighted factors inhibiting patients from participating in goal settings. These factors include: limited time, presiding professional routines, goal setting meeting which is held away from the patient, single opportunity to meet clinicians post discharge for secondary risk management, stroke pathology with its highly unpredictable recovery prognosis and its effects such as aphasia and (LOW to MODERATE CONFIDENCE IN STUDIES)

Three studies [150 49 200] highlighted psychosocial factors inhibiting patients from participating in goal settings. These factors include: inability to accept the occurrence of stroke, depression, patients guarding against exposing their incompetence (MODERATE CONFIDENCE IN STUDIES)

Strategies to develop person-centeredness in goal-setting practices

Two studies [150 175] highlighted that a multidisciplinary team approach involving the patient along with specialists such as speech pathologists improves discussion and documentation of patient goals (MODERATE CONFIDENCE IN STUDY)

Four studies [214 205 46 91] showed that patient-centred goals led to short-term improvement in activities of daily living, better global outcome, better motor outcomes and better self-perceived performance and satisfaction (VERY LOW to LOW CONFIDENCE IN STUDIES)

One study[150] mentioned that patient and family should be educated with regards the pathology, process of rehabilitation, setting goals and patients should be encouraged to identify goals that are in line with their expectation (MODERATE CONFIDENCE IN STUDY)

Goals of people with aphasia post stroke

One study [287] found that people with aphasia post stroke wanted greater autonomy dignity and respect. They also wanted more information about aphasia, stroke to return to their pre-stroke life to communicate their basic needs and their opinions (HIGH CONFIDENCE IN STUDY)

6.2.4 Economic evidence statements

No cost effectiveness evidence was identified.

6.2.5 Recommendations and links to evidence

Recommendations	**25. Ensure that people with stroke have goals for their rehabilitation that:** • **are meaningful and relevant to them** • **focus on activity and participation** • **are challenging but achievable**

	• **include both short-term and long-term elements.** **26.Ensure that goal-setting meetings during stroke rehabilitation:** • **are timetabled into the working week** • **involve the person with stroke and, where appropriate, their family or carer in the discussion.**
Relative values of different outcomes	The outcomes of interest were psychological measures and health related quality of life, physical function and Activities of Daily Living (ADL) Any impact goal setting has on activity and participation is clearly Important but other outcomes including patient's sense of self, autonomy, coping and self-image were also felt to be important.
Trade-off between clinical benefits and harms	The GDG agreed that goal setting that was patient centred and involved sharing information, and identifying patients values, beliefs and preferences was likely to have significant benefits to the patient, being both encouraging and motivating. However goal setting that is dominated by professionals may be both time consuming, and disempower patients, focussing on rehabilitation interventions that have little apparent relevance, although they can assist therapists in developing a treatment plan.
Economic considerations	No cost effectiveness studies were found. Personnel cost for delivering a goal setting intervention was estimated at £393 for the initial intervention and £197 for the review of the goals set based on GDG estimates of the resource use involved. The GDG considered that the additional costs would potentially be offset by the long term benefit to patients in terms of improved quality of life.
Quality of evidence	The systematic review (Rosewilliam, 2011) of both quantitative and qualitative studies included in the review explored the nature, extent and effects of applying patient-centred goal setting in stroke rehabilitation practice. In the qualitative studies data had been collected by interviews, focus groups and surveys. The quantitative studies had used randomised, cross sectional survey, retrospective analysis of records and case series designs. Two other qualitative studies evaluated the Goal Attainment Scaling (GAS) in home-based stroke rehabilitation (Hale, 2010), and goals of people with aphasia and how these goals can be coded (by clinicians) according to the International Classification of Functioning, Disability and Health (ICF) (Worrall, 2011). These were both descriptive studies using semi-structured, in-depth interviews. The themes explored by the studies included perceptions of patients regarding person-centeredness in goal setting and factors influencing it, professionals' perceptions concerning person-centeredness in goal setting, challenges to patient participation in goal setting and strategies to develop person-centeredness in goal-setting practices. The quality of included studies (Rosewilliam, 2011) were assessed by using quality criteria adapted from published literature with different sets of quality criteria used for the qualitative and quantitative studies. Themes from all qualitative studies matching the review questions were pooled. The findings from all of the studies were synthesised by aggregating the themes from the qualitative studies and relating them to findings from quantitative studies. The study qualities of Hale 2010 and Worrall 2011 were assessed and rated using the quality criteria adapted from the included systematic review and we merged findings from the themes that Hale 2010 identified. Confidence in the effects reported within the studies ranged from very low to high. The GDG noted that the majority of studies were small qualitative studies focussing on patients' perceptions, professionals' perceptions, the need for patient

	centredness and how to develop this.
Other considerations	The GDG noted that the findings from the studies of goal setting in stroke were similar to those reported in goal setting in other disabling conditions. The importance of developing structures to support patient involvement in goal setting including staff training was highlighted. Goal setting needs to be adapted according to the environment and the stage of acceptance with the individual. The studies highlighted that setting goals at the very acute stage is not always appropriate. After a stroke, the person has an enormous adjustment to make in accepting and coming to terms with what has happened. The GDG agreed that there were different levels of participation by the patient in goal setting, and at the acute stage this may be limited until the person feels ready and more confident when they can participate more.

6.2.6 Delphi statements where consensus was achieved

Table 29: Table of consensus statements, results and comments (percentage in the results column indicates the overall rate of responders who 'strongly agreed' with a statement and 'amount of comments' in the final column refers to rate of responders who used the open ended comments boxes, i.e. No. people commented / No. people who responded to the statement)

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
	Both profession specific as well as multidisciplinary stroke teams' goals should be person focused.	81.8	17/99 (17%) panel members commented This was seen important in the process of goal planning by some panel members ("Absolutely. We don't do this enough yet and we need to get much better at this to use outcome measures properly and really effectively.") It was seen as most important that goals should be set by or set collaboratively with the person who has had a stroke ("Goals need to be genuinely person generated." "Goal setting should be collaborative, set with the patient, and multidisciplinary rather than uni-disciplinary" "There should be one set of patient agreed patient centred goals") Four people expressed the opinion that this was not a sensible statement.
	Efforts should be made to establish the wishes and expectations of the person who has had a stroke and their carer/family.	86.9	13/99 (13%) panel members commented

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
			It was highlighted that these expectations need to be realistic. Some people questioned the term 'efforts' and what this would mean in real terms. One person indicated the opinion that this was a redundant statement.
	The following criteria should be used when setting goals with the person who has had a stroke: Meaningful and relevant Should be focused on activities and participation Challenging but achievable Both short and long-term targets May involve one MDT team member or may be multidisciplinary Involve carer / family where possible, with consent of person who has had a stroke Used to guide therapy and treatment	 92.0 69.7 76.0 70.1 76.0 81.0	20/100 (20%) panel members commented Rather than themes individual issues were highlighted: The type of goal depends on the stage and setting of rehabilitation ("Initial goals in the acute setting may be less focussed on activities and participation as the treatment begins to develop a base from which further goals may be set, for example increasing the length of treatment that can be tolerated. Not all objectives can be identified within recognised assessment tools in the early stages.") Some goals might not be easily measurable ("Goals do not have to be measurable as improvement in engagement and motivation can be a goal that will be difficult to quantify.") Goals should be jargon free. One person indicated the opinion that this was a redundant statement.

6.2.7 Delphi statements where consensus was not achieved

Table 30: Table of 'non-consensus' statements with qualitative themes of panel comments

Number	Statement	Results %	Amount and content of panel comments – or themes
	Goals should have predicted dates for completion.	36.5	In round 2 - 24/98 (24%) panel members commented; 19/85(22%) in round 3: Themes: Flexibility – timing of goals should not be too rigid and prescriptive.

Number	Statement	Results %	Amount and content of panel comments – or themes
			Type of goals – some goals don't lend themselves to predict an end point Effect on patients – focus on dates and failure can lead to distress and have an impact on confidence and esteem Progression – Rather than giving one date, regular reviews lead to a feeling of progress
	A review of goals of the person who has had a stroke should be conducted between the person and the multidisciplinary team member delivering the intervention at the expected date of completion.	42.4	In round 2 - 14/99 (14%) panel members commented; 13/85(15%) in round: The panel's comments have the following themes – some of these are mirroring those for expected dates of goals: Expected date – it was queried whether there would be an expected date ("I don't agree that goals always need to have an expected date of completion.") Regular reviews – goals should be regularly reviewed as an ongoing process ("But should be constantly reviewed throughout therapy."). Flexibility – when and how the review would take place should be flexible ("These people should be involved but there does need to be some flexibility"). Team or individual member - Could involve an individual team member, but sometimes also the whole team ("This should be part of the weekly MDT meeting which the patient should take part in."). One person objected to this statement since it represents and ideal scenario rather than what can be achieved in clinical practice ("if you did all these things, you'd never have time to do any actual therapy.").
	The reasons for unattained goals and goals that have been reassessed need to be documented.	56.5	In round 2 - 11/99 (11%) panel members commented; 6/85(7%) in round 3: Generally this was seen as positive, but it was stated that this may be too reflective for some and that it needs

Number	Statement	Results %	Amount and content of panel comments – or themes
			to benefit the individual rather than be a measure of outcome. "It is helpful to know why a goal is not being met – to learn about patterns of recovery and what affects progress."
	Patients should have a written copy of their goals.	52.4	In round 3 (this statement was first introduced in round 3) 17/84 (20%) panel members commented There was a feeling that the format of this documentation would not always be accessible to the person who has had a stroke (cognitive or language impaired persons for instance). "It might be helpful if this stated that these goals should be in language appropriate to the patient (not MDT language) and that where possible, they should reflect the patient's own words in setting the goals." "For patients with memory problems this is particularly important but also written goals aid communication between the patient, team and family".

6.2.8 Recommendations and links to Delphi consensus survey

Statements	21. Both profession specific as well as multidisciplinary stroke teams' goals should be person focused. 22. Efforts should be made to establish the wishes and expectations of the person who has had a stroke and their carer/family. 23. The following criteria should be used when setting goals with the person who has had a stroke: • Meaningful and relevant • Should be focused on activities and participation • Challenging but achievable • Both short and long-term targets • May involve one MDT team member or may be multidisciplinary • Involve carer / family where possible, with consent of person who has had a stroke • Used to guide therapy and treatment
Recommendations	**27. Ensure that during goal-setting meetings, people with stroke are provided with:**

	• **an explanation of the goal-setting process** • **the information they need in a format that is accessible to them** • **the support they need to make decisions and take an active part in setting goals.** **28. Give people copies of their agreed goals for stroke rehabilitation after each goal-setting meeting.** **29. Review people's goals at regular intervals during their stroke rehabilitation.**
Other considerations	The Delphi technique was used to elucidate the stroke rehabilitation community's views of goal setting and consensus was achieved on the importance of meaningful, relevant achievable goals that focussed on activity and participation and included both short term and long term targets. The GDG considered the areas that achieved consensus that would supplement the recommendations already made based on the evidence review undertaken. The GDG noted those statements that did not achieve consensus, and agreed these did not seem to be particularly controversial. It was agreed that emphasis should be placed on having goals that are meaningful and relevant to the patient. The GDG agreed that it was very important that patients should receive a copy of their goals, and argued that it was not possible to provide patient centred goals if they did not have a copy they could refer to. The group agreed with many of the comments from the survey that information on goals should be in a format accessible to the patient to take into account cognitive or language impairments… Although there was no agreement about reviewing goals at specified dates the GDG agreed that a review should be conducted at appropriate time points to monitor and discuss progress and reassess the needs and wishes of the patient.

6.3 Planning rehabilitation

6.3.1 Delphi statements where consensus was achieved

Table 31: Table of consensus statements, results and comments (percentage in the results column indicates the overall rate of responders who 'strongly agreed' with a statement and 'amount of comments' in the final column refers to rate of responders who used the open ended comments boxes, i.e. No. people commented / No. people who responded to the statement)

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
	Documentation related to rehabilitation should be individualised, and contain the following minimum information: Basic demographics including	93.9 96.9 92.9	17/99 (17%) panel members commented: A number of **additional**

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
	contact details and next to kin Diagnosis and relevant medical information List of current medications including allergies Standardised screening assessments to include those identified in earlier questions Person focused rehabilitation goals Multidisciplinary progress notes Key contact from the stroke rehabilitation team to co-ordinate health and social care needs Discharge planning information Joint health/social care plans if developed Follow-up appointments	 78.7 93.9 79.5 87.8 85.8 76.5 79.5	**documents** were suggested: Return to work information was mentioned most frequently Information on additional support available after discharge (for example, carer support organisations and stroke support groups) Stroke education / lifestyle information
1.	In the development of rehabilitation plans, efforts should be made to encourage the person who has had a stroke and carers to be involved and actively participate.	86.9	17/99 (17%) panel members commented: This was seen as **important in person centred care**. It was mentioned that the **wishes** of the person who has had a stroke **should be taken into consideration**. Some people find this a **stressful experience**. Three people expressed an opinion that this was a redundant statement.
2.	Rehabilitation plans should be reviewed by the multidisciplinary team at least once per week.	71.4	In round 2 - 41/95 (43%) panel members commented; 34/77(44%) in round 3

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
			The **phase of rehabilitation was commented on**. Weekly reviews early on in the acute phase, or when the person who has had a stroke is an inpatient, reducing to longer intervals as the rehabilitation progresses. "not sensible. In first 6 weeks weekly is needed there after two weekly is reasonable – or longer" "in light of the quick throughput of hospital stroke patients the review may need to be undertaken twice a week". There was a concern not to be too prescriptive about timing. "because each person who has had a stroke is different, the review should take place according to needs of the individual and this will vary" **Type of plan and type of goal** was also seen as important: "This depends on how you define rehabilitation plans. Are they broad, for example to go home independently walking and self-care and returning to work or more specific to the moment for example to be able to stand for 5 minutes in a standing frame?"

6.3.2 Delphi statement where consensus was not reached

Table 32: Table of 'non-consensus' statements with qualitative themes of panel comments

Number	Statement	Results %	Amount and content of panel comments – or themes
1.	When there is a significant change, or when a plateau/potential is reached, or before discharge, a meeting involving the stroke rehabilitation team, with an invitation to the person and their family/carer, should be conducted to discuss these points.	63.4	In round 2 - 22/99 (22%) panel members commented; 16/85(19%) in round 3 and 11/72 (15%) in round 4: There were several themes: **MDT** – some members of the panel thought that this does not have to involve the whole team ("The meetings should happen but only include the relevant staff, not the whole stroke rehabilitation team"). **Before discharge** – this was seen as the most important aspect of the statement. **Need for an additional meeting** – if there are regular reviews then changes / plateau should not come as a surprise **Meeting type** – this needs to be tailored (formal or informal) to the individual and their carer/family **Statement** – the statement itself was seen as having too many different components to answer with one response. Several people commented that the terms 'plateau' or 'potential' was unclear. ("What is plateau? One day of no change, one week, one month?")

6.3.3 Recommendations and links to Delphi consensus survey

Statements	24. Documentation related to rehabilitation should be individualised, and contain the following minimum information: • Basic demographics including contact details and next to kin • Diagnosis and relevant medical information

	• List of current medications including allergies • Standardised screening assessments to include those identified in earlier questions • Person focused rehabilitation goals • Multidisciplinary progress notes • Key contact from the stroke rehabilitation team to co-ordinate health and social care needs • Discharge planning information • Joint health/social care plans if developed • Follow-up appointments 25. In the development of rehabilitation plans, efforts should be made to encourage the person who has had a stroke and carers to be involved and actively participate. 26. Rehabilitation plans should be reviewed by the multidisciplinary team at least once per week.
Recommendations	**30. Provide information and support to enable the person with stroke and their family or carer (as appropriate) to actively participate in the development of their stroke rehabilitation plan.** **31. Stroke rehabilitation plans should be reviewed regularly by the multidisciplinary team. Time these reviews according to the stage of rehabilitation and the person's needs.** **32. Documentation about the person's stroke rehabilitation should be individualised, and should include the following information as a minimum:** • **basic demographics, including contact details and next of kin** • **diagnosis and relevant medical information** • **list of current medications, including allergies** • **standardised screening assessments (see recommendation 18)** • **the person's rehabilitation goals** • **multidisciplinary progress notes** • **a key contact from the stroke rehabilitation team (including their contact details) to coordinate the person's health and social care needs** • **discharge planning information (including accommodation needs, aids and adaptations)** • **joint health and social care plans, if developed** • **follow-up appointments.**

Economic considerations	There are some costs associated with the reviewing of the rehabilitation plan by the multi-disciplinary team. The GDG has considered the economic implications and concluded that the benefits of the intervention in terms of improvement in quality of life were considered likely to outweigh the costs.
Other considerations	The GDG overall agreed with the statement on what information should be included in planning rehabilitation, whilst acknowledging this was not exhaustive and should be thought of as a core list. It was felt that there would be a variety of opinions on additional information that should be included, but were in agreement with the consensus view. It was thought that care planning is an element of goal setting. Although some comments had been made that the statements were rather obvious, the GDG thought that providing support to enable the person and carers to be involved in the development of their rehabilitation plans through having knowledge and feeling empowered to participate was a key recommendation to make. The GDG thought that specifying when rehabilitation plans should be reviewed was not helpful, and agreed with the comments from the Delphi survey, that this would be variable, with reviews being carried out very frequently in the early stages and less so later on. The group agreed that it should be based on the needs of the patient at different stages of the rehabilitation pathway.

6.4 Intensity of stroke rehabilitation

The dose of rehabilitation that individuals receive varies from country to country and service to service. In specialist neurorehabilitation services patients may receive 5 hours of therapy each day, in others 1 or 2 hours each day. Duration of therapy may vary from 2 weeks to 3 or 6 months with some patients accessing or re-accessing input some years after the onset of stroke.

The National Stroke Strategy[61] states 'People who have had strokes access high-quality rehabilitation and, with their carer, receive support from stroke-skilled services as soon as possible after they have a stroke, available in hospital, immediately after transfer from hospital and for as long as they need it'. The NICE stroke quality standard [189] specifies that 'Patients with stroke are offered a minimum of 45 minutes of each active therapy that is required, for a minimum of 5 days a week, at a level that enables the patient to meet their rehabilitation goals for as long as they are continuing to benefit from the therapy and are able to tolerate it.' Many frail older patients with co-morbidities cannot tolerate such intensity in the early stages after stroke, other patients can tolerate far more. In other spheres where motor learning is important it is accepted that the degree of performance improvement is dependent on the amount of practice. In stroke where there is a range of impairments and as patients move around in changing environments there is uncertainty about the benefits of increasing the total dose of therapy whether in terms of intensity (hours per day) or duration of therapy (weeks).

6.4.1 Evidence review: In people after stroke what is the clinical and cost-effectiveness of intensive rehabilitation versus standard rehabilitation?

Clinical Methodological Introduction	
Population:	Adults and young people 16 or older who have had a stroke
Intervention:	Intensive rehabilitation (inpatient and outpatient) mixed package of therapy delivered by a MDT.

Clinical Methodological Introduction	
	(hours per day, number of days of treatment, weeks versus months, large versus small dose)
Comparison:	Standard rehabilitation or none
Outcomes:	• Length of stay • Functional Independence Measure (FIM) • Barthel Index • Quality of Life (any measure) • Nottingham Activities of Daily Living • Rankin • Rivermead Mobility Index • Frenchay Activities Index

6.4.1.1 Clinical evidence

Searches were conducted for systematic reviews and RCTs comparing the effectiveness of intense rehabilitation with usual care for rehabilitation after stroke for adults and young people 16 or older that have had a stroke. Only studies with a minimum sample size of 20 participants (10 in each arm) and including at least 50% of participants with stroke were selected. Four (4) RCTs were identified. Table 33 summarises the population, intervention, comparison and outcomes for each of the studies.

Table 33: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix H.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Özdemir, 2001[196]	Patients aged>80 years who had stroke or recurrent stroke and had been referred after medical stabilisation. Follow-up: 60 days	Therapeutic and neuromuscular exercises with occupational therapy with professional supervision for 2 hours a day, 5 days a week (intense multidisciplinary inpatient rehabilitation service). (N=30)	Conventional exercises with family caregiver and limited professional supervision given at home for 2 hours once a week. (N=30)	• Functional Independence Measure (FIM)
Ryan, 2006[225]	Patients aged >=65 years recently discharged from hospital after suffering a stroke or hip fracture (only the subgroup results of people with stroke were used included in the review here) Follow-up: 3 months	Domiciliary intensive rehabilitation: six or more face-to-face contacts per week from members of a multidisciplinary rehabilitation team. Maximum length of treatment lasted for 12 weeks. (N=45)	Standard rehabilitation: three or less face-to-face contacts per week from members of a multidisciplinary rehabilitation team. (N=44)	• Barthel Index • Frenchay Activities Index (FAI) • EuroQol 5D (EQ-5D) • Euroqol Visual Analogue Scale (EQ-VAS)
Smith, 1981[241]	Patients admitted to hospital, with a recent confirmed stroke, who were	Intensive rehabilitation: physiotherapy and occupational	Standard rehabilitation: physiotherapy and occupational	• Activities of Daily Living (ADL)

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
	able to manage the most intensive of the 3 regimens. Follow-up: 12 months	therapy in groups and individually for four full days a week up to six months (except for four patients who made a full recovery earlier) (time spent in therapy was recorded). (N=46)	therapy in groups and individually for three half days a week up to six months (except for five patients who made a full recovery earlier) (time spent in therapy was recorded). (N=43) 'No routine' rehabilitation: regular home visits by a health visitor, (on average of seven visits (range 3-13) to each patient). These visits usually lasted one to two hours during the six months after discharge from hospital.(N=44)	
Werner, 1996[282]	Patients who were at least 1 year post-stroke, with evidence of functional limitations in the area of dressing, walking, eating, or bathing. Follow-up: 9 months	Intensive 12-week outpatient rehabilitation program consisting of an hour each of physical and occupational therapy, four times per week, for 12 weeks; therapy focused on neuromuscular facilitation and functional tasks. (N=33)	No rehabilitation. (N=16)	• Functional Independence Measure; motor measure (FIM-MM)

Comparison: Intensive rehabilitation versus standard rehabilitation or none

Table 34: Intensive rehabilitation versus standard rehabilitation - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
								Effect		
No. of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Intensive rehabilitation Mean (SD)	Standard rehabilitation Mean (SD)	Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
Barthel index (3 months follow-up) (Better indicated by higher values)										
1 Ryan et al[225]	RCT – single-blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	No serious imprecision	2.75 (2.1)	2.65 (2.1)	0.10 (-0.77, 0.97)	MD 0.1 higher (0.77 lower to 0.97 higher)	Moderate
Euroqol VAS (3 months follow-up) (Better indicated by higher values)										
1 Ryan et al[225]	RCT – single-blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	No serious imprecision	0.09 (0.2)	0.01 (0.1)	0.08 (0.01, 0.15)	MD 0.08 higher (0.01 to 0.15 higher)	Moderate
Euroqol -5D (3 months follow-up) (Better indicated by higher values)										
1 Ryan et al[225]	RCT – single-blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	No serious imprecision	0.14 (0.25)	0.0 (0.25)	0.14 (0.04, 0.24)	MD 0.14 higher (0.04 to 0.24 higher)	Moderate
Frenchay activities index (3 months follow-up) (Better indicated by higher values)										
1	RCT –	Serious	No serious	No serious	Serious	8.87 (7)	8.08 (7.7)	0.79 (	MD 0.79	Low

Quality assessment						Summary of findings				
								Effect		
No. of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Intensive rehabilitation Mean (SD)	Standard rehabilitation Mean (SD)	Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
Ryan et al[225]	single-blinded	limitations (a)	inconsistency	indirectness	imprecision (c)			-2.27, 3.85)	higher (2.27 lower to 3.85 higher)	
Functional Independence Measure (total score) (post treatment effect) (Better indicated by higher values)										
1 Ozdemir et al. [196]	RCT – unblinded	Very serious limitations (d)	No serious inconsistency	No serious indirectness	No serious imprecision	59.63 (14.19)	12.3 (13.38)	47.33 (40.35, 54.31)	MD 47.33 higher (40.35 lower to 54.31 higher)	Low
Activities of Daily Living index (3 months follow-up) (Better indicated by higher values)										
1 Smith et al [241]	RCT – unblinded	Very serious limitations (e)	No serious inconsistency	No serious indirectness	(g)	3.54	2.87	(h)	(h) P<0.01(i)	Low (g)
Activities of Daily Living index (12 months follow-up) (Better indicated by higher values)										
1 Smith et al [241]	RCT – unblinded	Very serious limitations (e,f)	No serious inconsistency	No serious indirectness	(g)	3.50	2.89	(h)	(h)	Low (g)

(a) Unclear randomization. The study did not achieve the pre-specified ratio of 2:1 (intensive/non-intensive) 25% stroke patient loss to follow-up.
(b) Mean difference did not reach the agreed MID of 1.85 points.
(c) Confidence interval crossed both ends of default MID.
(d) Unblinded with inadequate randomisation and unclear allocation concealment.
(e) Unblinded with no details on randomisation process and allocation concealment.
(f) 20% patients dropped out at 1 year.
(g) Imprecision could not be assessed because only means of data were reported.

(h) Relative/absolute effect could not be estimated as no standard deviation was provided in the study.
(i) P value as reported by the authors.

Table 35: Intensive rehabilitation versus no rehabilitation - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
								Effect		
No. of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Intensive rehabilitation Mean (SD)	No rehabilitation Mean (SD)	Mean difference (95% CI)	P value	Confidence (in effect)
Activities of Daily Living index (3 months follow-up)										
1 Smith et al [241]	RCT – unblinded	Very serious limitations (a)	No serious inconsistency	No serious indirectness	(d)	3.54	1.50	(e)	(e) P<0.01 (f)	Low (d)
Activities of Daily Living index (1 year follow-up)										
1 Smith et al [241]	RCT – unblinded	Very serious limitations (a,b)	No serious inconsistency	No serious indirectness	(d)	3.50	0.60	(e)	(e) P<0.05 (f)	Low (d)
Functional Independence Measure (Motor) (3 months follow-up)										
1 Werner et al [282]	RCT – unblinded	Very serious limitations (c)	No serious inconsistency	No serious indirectness	(d)	6.6	1.5	(e)	(e)	Low (d)
Functional Independence Measure (Motor) (3 to 9 months follow-up)										
1 Werner et al [282]	RCT – unblinded	Very serious limitations (c)	No serious inconsistency	No serious indirectness	(d)	0.7	-1.0	(e)	(e) P=0.03 (f)	Low (d)

(a) Unblinded study, no details on randomisation process and unclear allocation concealment.
(b) 20% patients dropped out at 12 months

(c) Single blinded study with unclear allocation concealment, high drop-out rate in both arms –10 of the 33 patients in the intervention group loss to follow-up (5 dropped out at 3 months and another 5 dropped out at 9 months); 9 of the 16 controls loss to follow-up; 5 additional control patients were recruited after the treatment ended.
(d) Imprecision could not be assessed because only means of data were reported.
(e) Relative/absolute effect could not be estimated as no standard deviation was provided in the study.
(f) P value as reported by the authors.

6.4.1.2 Economic evidence

Literature review

No relevant economic evaluations comparing different intensities of multidisciplinary rehabilitation were identified.

New cost-effectiveness analysis

Full methods and results are presented in Appendix K; a summary is provided below.

The GDG identified the comparison of more intensive programmes of rehabilitation for people with stroke with less intensive programmes as a high priority area for economic analysis.

More intensive rehabilitation may be more costly to deliver than less intensive rehabilitation because it may require additional staff time. However, additional costs may be offset by an improvement in outcomes for the patient (such as independency in activities of daily living), leading to increased QALYs and potentially a reduction in future healthcare and social care costs.

The following general principles were adhered to in developing the cost-effectiveness analysis:

- The GDG was consulted during the construction and interpretation of the model.
- Model inputs were based on the systematic review of the clinical literature supplemented with other published data sources where possible.
- When published data was not available expert opinion was used to populate the model.
- Model inputs and assumptions were reported fully and transparently.
- The results were subject to sensitivity analysis and limitations were discussed.
- The model was peer-reviewed by another health economist at the NCGC.

Model overview

A cost-utility analysis was undertaken to evaluate the cost-effectiveness of more intensive versus less intensive stroke rehabilitation. Lifetime quality-adjusted life years (QALYs) and costs were estimated from a current UK NHS and personal social services perspective. As is standard practice in economic evaluation, both costs and QALYS were discounted to reflect time preference; a rate of 3.5% per annum was used in line with NICE methodological guidance[187]. The cost effectiveness outcome of the model was cost per QALY gained.

The analysis was primarily based on data from the UK clinical study reported by Ryan and colleagues, 2006[225] described in the clinical review above.

A probabilistic analysis was undertaken to evaluate uncertainty in the model input estimates. In addition, various sensitivity analyses were undertaken to test the robustness of model assumptions and data sources. In these, one or more inputs were changed and the analysis rerun to evaluate the impact on results.

The GDG noted that the intensity level in the more intensive rehabilitation arm in the study reported by Ryan and colleagues was likely to be lower than that now specified by the stroke quality standard[188]. We therefore undertook exploratory threshold analyses to provide information to help inform the GDG decision making.

Population

The population for the cost-effectiveness analysis comprised adults and young people aged 16 or older who have had a stroke and required rehabilitation.

Comparators

The comparators in the model were:

- Less intensive multidisciplinary rehabilitation
- More intensive multidisciplinary rehabilitation

Following Ryan et al. (2006)[225], the intervention was assumed to be delivered at home. Less intensive rehabilitation was three or less face-to-face contacts per week, for 12 weeks maximum. More intensive rehabilitation in the study was six or more face-to-face contacts per week, for 12 weeks maximum.

Model structure

A life table approach was taken to the analysis. Life tables for England and Wales were adjusted for the increased mortality in people who have had a stroke. This estimated the number of people alive after each 3 month period (each cycle) and this was used to estimate life years for people in the model. It was assumed that mortality is not impacted by the type of rehabilitation received and so life expectancy did not vary by comparator in the model.

A quality of life (utility) value was attributed to people who were alive in the model that depended on the type of rehabilitation received ('more intensive' or 'less intensive'). This resulted in differences in QALYs between patients.

Differences in total costs between the more and less intensive rehabilitation groups were due to differences in the cost of delivering rehabilitation – this cost was incurred in the first 3 month cycle. It was assumed in the base-case analysis that in the post-rehabilitation period costs did not vary between the more intensive and the less intensive rehabilitation.

Model inputs

Model inputs were based on clinical evidence identified in the systematic review undertaken for the guideline, supplemented by additional data sources as required. Model inputs were validated with clinical members of the GDG. A summary of the model inputs used in the base-case (primary) analysis is provided in Table 36 below. More details about sources, calculations and rationale can be found in the full technical report in Appendix K.

Table 36: Summary of base-case model inputs

Input	Data	Source	Probability distribution
Comparators	• Less intensive rehabilitation • More intensive rehabilitation		
Population	People who have had a stroke and need rehabilitation		
Perspective	UK NHS & PSS	NICE reference case[187]	
Time horizon	Lifetime		
Discount rate	Costs: 3.5% Outcomes: 3.5%	NICE reference case[187]	n/a
Cohort settings			

Input	Data	Source	Probability distribution
Age on entry to model	77 years	Ryan et al. 2006[225]	Fixed
% female	61%	Ryan et al. 2006[225]	Fixed
Mortality			
Mortality rate	Age dependent	England and Wales 2007-09 life tables[192]	Fixed
Mortality rate adjustment for stroke (SMR)	Female: 2.85 (CI: 2.66, 3.05) Male: 2.58 (CI: 2.43, 2.75)	Bronnum-Hansen et al. 2001[34]	Lognormal
Quality of life (utility)			
Before rehabilitation	0.54	Ryan et al. 2006[225]	Fixed
Change after less intensive rehabilitation	0 (SE 0.04)	Ryan et al. 2006[225]	Normal
Difference in change with more versus less intensive rehabilitation	0.14 (SE 0.05)	Ryan et al. 2006[225]	Normal
Long term utility assumption	• Scenario 1: difference is maintained over lifetime • Scenario 2: difference disappears over time (3 months, 1 year or 5 years)	Assumptions	n/a
Costs			
Rehabilitation costs	Less intensive: £634 More intensive: £865	Derived from resource use and unit costs below	n/a
Total number of rehabilitation sessions	Less: 17.9 (SE 1.19) Difference, more – less: 6.5 (SE 1.76)	Ryan et al. 2006[225]	Gamma Normal
Length of rehabilitation session	45 minutes	Assumption based on trial range (30-60minutes) (Personal communication AW Ryan, email January 2011)	Fixed
Personnel delivering rehabilitation	Professional: 75% sessions Assistant: 25% sessions	Assumption	Fixed
Cost per hour home visit: rehabilitation professional(a)	£54	PSSRU 2010: Community; hour cost of home visiting[50]; band 6(b); including qualifications	Fixed
Cost per hour home visit: rehabilitation assistant	£27	PSSRU 2010: Clinical support worker nursing (community); per hour spent on home visits[50]; band 3(b); including qualifications	Fixed
Post-rehabilitation costs	No difference	Assumption	Fixed

CI = 95% confidence interval; n/a = not applicable; PSSRU = Personal Social Services Research Unit; SMR = standardised mortality ratio; SE = standard error
(a) Physiotherapist, occupational therapist and speech and language therapist
(b) Costs were calculated using PSSRU data and approach but with the salary band stated

Results

The analysis found that more intensive rehabilitation was cost effective compared to less intensive rehabilitation, based on levels of intervention and outcomes from the Ryan et al. 2006 study[225]. There was an additional cost associated with more intensive rehabilitation as more rehabilitation sessions were provided; however this was offset by the additional improvement in quality of life that results in higher QALYs. This conclusion was seen with all long-term utility scenarios. There was low within analysis uncertainty about this conclusion. It was also robust to a range of sensitivity analyses around input parameters

Table 37: Base case results – more intensive versus less intensive rehabilitation (probabilistic analysis)

Analysis	Mean cost difference (more - less)(a)	Mean QALY difference (more - less	Incremental cost effectiveness ratio (ICER)	% simulations 'more intensive' cost-effective (£20K/QALY)
Scenario 1 - difference in utility maintained over time				
Maintained over lifetime	£226	0.70	£324	99%
Scenario 2 - utility difference disappears over time				
Disappears over 3 months	£228	0.03	£6,722	95%
Disappears over 1 year	£228	0.08	£2,751	99%
Disappears over 5 years	£226	0.29	£776	100%

(a) Minor difference are due to results being from different runs of the probabilistic analysis

Threshold analyses

Full results tables are shown in the full technical report in Appendix K.

Costs:

An analysis was undertaken to determine the cost difference threshold where intensive rehabilitation was no longer cost-effective (using a £20,000 per QALY gained cost-effectiveness threshold). Under the most conservative long-term utility assumption (where the utility difference observed at the end of rehabilitation had disappeared over 3 months), more intensive rehabilitation would no longer be cost effective if the difference in rehabilitation cost was more than £685 (equivalent to a difference of about 17 sessions, of 45 minutes, with a rehabilitation professional). Under the most favourable utility assumption (where the difference observed at the end of rehabilitation was maintained indefinitely), more intensive rehabilitation remained cost effective until the difference in rehabilitation costs exceeded £13,433 (equivalent to a difference of over 300 sessions with a rehabilitation professional).

QALYs:

We also undertook a threshold analysis where we varied the difference in the number of rehabilitation sessions between the groups and then calculated what QALY difference would be required for it to be considered cost-effective. The GDG estimated that in current UK practice a level of input in line with the current NICE quality standard would be 45 minutes of each relevant therapy at least 5 days a week as long as they are continuing to benefit from it. Thus over 6 weeks an individual might receive 60 - 90 sessions of input. The GDG recognised that the recent Stroke Sentinel audit highlighted that about a third of patients received less than this while in hospital[123]. No data is available for community based rehabilitation services. The GDG estimated that a typical level of input would be three physiotherapy sessions per week, one occupational therapy session per week, and one speech and language therapy session per week (that is 30 sessions). This would be a difference

of 60 sessions total between ideal and typical input. The difference in number of sessions was therefore varied between 6.5 (from the Ryan et al. 2006 study) and 60 (based on the GDG estimate).

The lifetime QALY gain required for more intensive rehabilitation to be cost effective ranged from 0.01-0.11 when the difference in number of rehabilitation sessions was varied between 6.5 and 60.

We then also calculated the number of months for which, different quality of life (utility) gains would need to be maintained, in order to achieve these QALY gains. With a difference of 60 rehabilitation sessions with more intensive compared to less intensive rehabilitation, it was found that a utility gain of 0.14 (as observed in the Ryan et al. 2006 study) would need to be maintained for 9 months in order for more intensive rehabilitation to be cost effective. When utility gain was varied between 0.02 and 0.24, this varied from 5 months to 64 months.

Discussion

Ryan et al. (2006) study generalisability

The key limitations of this analysis are the limitations of the clinical effectiveness data for the comparison of more and less intensive rehabilitation. Only one study reported utility data that could be used to calculate QALYs and the amount of rehabilitation received in this study compared with the current quality standard, and even current UK practice is very different. In study reported by Ryan and colleagues more intensive rehabilitation was a total of 17 sessions on average per person and less intensive was 11. The GDG estimated that a level of intervention similar to that recommended by the current NICE quality standard would be more like 90 rehabilitation sessions per patient (spread across specialities), and that typical levels of input in the UK would be around 30 sessions.

It was noted that rehabilitation is a complex intervention, that is, the outcome does not vary linearly with inputs. One possibility is that there is a critical threshold for improvement. For example, if one leg is weak the patient will be unable to walk. The strength may increase linearly for 6 weeks, but only in week 7 will the patient walk. If a functional outcome is used, the patient will appear to plateau for 6 weeks and then may show a significant change in functional status. This again makes it difficult to extrapolate from the study reported by Ryan and colleagues.

Stratification

It was noted that younger patients also often have the capacity to participate in more sessions of rehabilitation as this is linked to cardiovascular fitness, frailty and co-morbidity, all of which tend to be worse in older patients. They also often have a greater range of needs (education, work, and parenting). Yet often younger patients do not get more rehabilitation. It was not possible to undertake subgroup analysis on this basis in the model as not clinical studies had examined this.

Quality of life assumptions

The study reported by Ryan and colleagues reported EQ5D quality of life data at 3 months but did not have any longer term follow-up and so assumptions were made regarding what happens to the difference in quality of life over time between the groups. However both conservative and more favourable assumptions were explored in the model to test the impact on results.

The analysis does not include any impact on carer quality of life as there was no evidence available. It is plausible that greater functional ability for the person who has had a stroke may also mean less burden on their carer and this may lead to an improvement in the carer's quality of life as well. If this were the case, this would increase the QALY gain with more intensive rehabilitation, making it more cost effective.

Post-rehabilitation costs

In the base-case analysis we assumed no difference in post-rehabilitation costs; however greater functional ability could plausibly result in lower dependency and potentially lower social care costs. This would further favour more intensive rehabilitation.

Rehabilitation setting

The study reported by Ryan and colleagues was based on community rehabilitation and so costs in the model are also based on community rehabilitation. The GDG considered that the amount of rehabilitation should be the same whether delivered in the community or in hospital. In addition if rehabilitation was taking place in hospital the intensity of rehabilitation would most likely not change the length of stay but would just impact the amount of input from different professionals whilst in hospital. Therefore in either setting the cost impact would largely be about people's time rather than changes in hospital capacity, overheads or hotel costs and so this was not considered likely to greatly impact the results. It was noted that potentially more intensive rehabilitation during the initial hospitalisation may even reduce hospital stay as patients become more functionally able more quickly.

6.4.1.3 Evidence statements

Clinical evidence statements

One study[225] with 89 participants found no significant difference between the intensive rehabilitation group and the standard rehabilitation group at 3 months on the Barthel Index (MODERATE CONFIDENCE IN EFFECT).

One study[225] with 89 participants found a statistically significant improvement in the intensive rehabilitation group compared with the standard rehabilitation group at 3 months, on the Euroqol Visual Analogue Scale (MODERATE CONFIDENCE IN EFFECT)
One study[225] with 89 participants found a statistically significant improvement in the intensive rehabilitation group compared with the standard rehabilitation group at 3 months, on the Euroqol-5D (MODERATE CONFIDENCE IN EFFECT)

One study[225] with 89 participants found no significant difference on the Frenchay Activities Index between the intensive rehabilitation group and the standard rehabilitation group at 3 months follow-up (LOW CONFIDENCE IN EFFECT)

One study[196] with 60 participants found that there was a statistically significant improvement in the Functional Independence Measure in the intensive rehabilitation group over a 60-day follow-up, compared with the less intensive home-based group (LOW CONFIDENCE IN EFFECT).

Evidence statements could not be produced for the following outcome(s) as results were not presented in a way that enabled the size of the intervention's effect to be estimated:

- Activities of Daily Living Index[241]
- Functional Independence Measure (Motor)[282]

Economic evidence statements

More intensive rehabilitation was found to be cost effective compared to less intensive rehabilitation, based on a modelled analysis using levels of intervention and outcomes from the Ryan et al. 2006 study (24 versus 18 rehabilitation sessions; EQ5D difference 0.14 at 3 months) and a range of long-term utility assumptions. However, these conclusions are limited by concerns regarding

applicability of the study reported by Ryan and colleagues to current UK practice. Exploratory threshold analyses found:

- Under the most conservative long-term utility assumption (where the utility difference observed at the end of rehabilitation had disappeared over 3 months), more intensive rehabilitation would no longer be cost effective if the difference in rehabilitation cost was more than £685 (equivalent to a difference of about 17 sessions, of 45 minutes, with a rehabilitation professional).
- Under the most favourable long-term utility assumption (where the difference observed at the end of rehabilitation was maintained indefinitely), more intensive rehabilitation remained cost effective until the difference in rehabilitation costs exceeded £13,433 (equivalent to a difference of over 300 sessions with a rehabilitation professional).
- Assuming a difference of 60 sessions between more and less intensive rehabilitation: a utility difference of 0.14 would need to be maintained for 9 months for more intensive to be cost effective; a difference of 0.24 for 5 months; and a difference of 0.02 for 64 months (about 4 years).

6.4.2 Recommendations and link to evidence

Recommendations	**33. Offer initially at least 45 minutes of each relevant stroke rehabilitation therapy for a minimum of 5 days per week to people who have the ability to participate, and where functional goals can be achieved. If more rehabilitation is needed at a later stage, tailor the intensity to the person's needs at that time[g].** **34. Consider more than 45 minutes of each relevant stroke rehabilitation therapy 5 days per week for people who have the ability to participate and continue to make functional gains, and where functional goals can be achieved.** **35. If people with stroke are unable to participate in 45 minutes of each rehabilitation therapy, ensure that therapy is still offered 5 days per week for a shorter time at an intensity that allows them to actively participate.**
Relative values of different outcomes	The outcomes of interest included in the review were: length of stay, Functional Independence Measure (FIM), Barthel Index, Quality of Life (any measure), Nottingham Activities of Daily Living, Rankin, Rivermead score, Frenchay Activities Index The limited number of studies available showed an improvement in every model of rehabilitation. Two studies (Smith 1981, Werner 1996[241,282]) which were both post-acute suggested an improvement with outpatient intensive rehabilitation. One study (Ryan 2006[225]) showed a benefit on EQ5D social participation health related quality of life measure but not on Barthel. It was noted that the Barthel baseline was 16 and the mean Barthel gain was 2.7. The GDG considered the reason a difference was not seen between the two groups may have been due to ceiling effects as the Barthel scale only goes to 20. An average score of 18.7 would indicate that the patients in

[g] Intensity of therapy for dysphagia, provided as part of speech and language therapy, is addressed in recommendation 1.7.2

	the study were less severely disabled. The group acknowledged this may also account for the gains found in the EQ5D. The patients in the study by Ozdemir[196] were more acute and it was recognised by the GDG that the FIM outcome gains were clinically highly significant reinforcing the value of rehabilitation but that there were limitations in the study design. The GDG noted that patient tolerance to the therapies should be taken into consideration as patients' tolerance would vary. The GDG agreed that there is no linear relationship between outcome and intervention.
Trade-off between clinical benefits and harms	The study reported by Ryan and colleagues, which provides information on the EQ5D outcome at 12 weeks, shows there is significant difference in EQ5D and this is clinically significant. The EQ5D is a standardized measure of health outcome, domains cover mobility, self-care, pain, anxiety and depression and usual activity. The intervention would aim to restore usual activity and the GDG agreed that they would expect this to be maintained after the 12 week period. The group in the paper (Ryan 2006) was a relatively able group so it is reasonable to assume these gains would be maintained. The Werner study[282] showed that over a 3 month period 3 years post stroke the intensive group improved on the FIM outcome scale and this was maintained over the following 9 months. It was noted that FIM covers two of the items within the EQ5D. The GDG agreed that a cohort that was more disabled would be expected to make greater gains from having had more intense rehabilitation. The GDG agreed that there were no particular harms associated with any of the interventions delivered within the studies and they considered the benefits of providing rehabilitation at the appropriate individual level were clear and those receiving more intensive therapy would be expected to achieve the greater gains.
Economic considerations	No published economic evaluations comparing more and less intensive rehabilitation were undertaken. The GDG identified this area as a high priority for analysis and a cost-effectiveness model was developed based on the study reported by Ryan and colleagues (this was the only study that reported quality of life data [EQ5D] suitable for calculating QALYs). This analysis found more intensive rehabilitation to be cost effective compared to less intensive rehabilitation. The GDG noted that these conclusions were limited by concerns regarding applicability of the study reported by Ryan and colleagues to current UK practice, in particular the fairly low levels of rehabilitation in both groups compared to current standards; other limitations to this study are noted elsewhere in this table. It was also noted that the analysis incorporated the additional cost of more intensive rehabilitation but did not incorporate any downstream cost differences due to a lack of evidence on which to base these. Potentially there may be cost savings downstream of more intensive rehabilitation; for example, if patients are more functionally able, social care costs may be reduced. If this were to be the case this would further favour more intensive rehabilitation. Due to the concerns described above about applicability, exploratory threshold analyses were undertaken to help inform GDG decision making. The cost difference threshold ranged between £685 (equivalent to a difference of about 17 sessions of 45 minutes with a rehabilitation professional) and £13,433 (equivalent to a difference of over 300 sessions with a rehabilitation professional), depending on the assumption made about how short-term quality of life differences are maintained in the longer term. The most conservative utility assumption was that the quality of life difference observed at 3 months disappeared

	by 6 months. The most favourable utility assumption was that the difference was maintained indefinitely. It was agreed that while there may be some convergence between groups, it was likely that overall some difference would be maintained. The GDG estimated that there would be difference of around 60 sessions between current practice and rehabilitation provision at the level of the NICE quality standard. With this difference in number of rehabilitation sessions with more intensive compared to less intensive rehabilitation, it was found that a utility gain of 0.14 (as observed in the study reported by Ryan and colleagues) would need to be maintained for 9 months in order for more intensive rehabilitation to be cost effective. When utility gain was varied between 0.02 and 0.24, this varied from 5 months to 64 months respectively. The GDG noted that this analysis was largely exploratory given the limitations of the data. It was also noted that, as the relationship between intensity level and outcomes were not linear, extrapolation was difficult. However, they concluded that based on the threshold analyses it seemed likely that if more intensive rehabilitation provided quality of life benefits it was likely it would be cost effective. Therefore it was agreed that increasing intensity to the level in the current quality standard was likely to be cost effective. In addition, the GDG considered that above this where people continue to make functional gains it is likely that quality of life gains would mean that provision would be cost effective.
Quality of evidence	Whilst all the studies had some limitations methodologically the GDG considered that there was modest evidence that showed more intensive rehabilitation at the later stages post stroke was beneficial as demonstrated in the studies by Ryan and Werner [225,282]. Moderate confidence in effect (Ryan 2006) was found for the quality of life outcome Euroqol 5-D which demonstrated a significant improvement. Confidence in the results shown for the Barthel and Frenchay outcomes was moderate and low and demonstrated no significant difference. A significant improvement was shown for the Functional Independence measure over a 60 day follow-up. (Ozdemir 2001). The GDG were concerned that the patients in both groups in the Ryan study[225] were higher functioning in both groups and therefore may not demonstrate a lot of difference. The patients in the Ozdemir paper[196] was considered to be more representative of functioning levels of stroke patients seen in clinical practice.
Other considerations	Only one study (Ozdemir[196]) was within the hospital setting, others were out-patient/community settings. None of the studies were started within 2 weeks of onset of stroke but some addressed rehabilitation needs in the sub-acute and chronic phases. The GDG agreed it was difficult to state what could be considered intensive from the studies reviewed. Two of the studies had 2 hours 4-5 days per week (Werner 1996, Ozdemir 2001), while the study by Ryan (2006) described the number of contacts made. The GDG noted that the amount of therapy highlighted in the studies would not reflect highly intensive practice versus what would now be accepted as conventional. The GDG noted that intensity of rehabilitation could be considered in terms of frequency, time, and duration, and that studies of intensity may be confounded by other variables such as expertise, mode of delivery, and any specific deficit being targeted. The GDG agreed that the evidence demonstrated that more rehabilitation was better, but what remains unclear is what 'more rehabilitation' constitutes. The GDG agreed the level of intensity delivered within the

	studies did not appear to be consistent with current medical practice or aspirations. It was noted that further research is required. Because the studies reviewed provided no details on the interventions delivered (other than stating a mix of physiotherapy and occupational therapy), it is not possible to make recommendations on what should be delivered within a package of intensive rehabilitation. The group agreed that best practice would offer interventions that are goal directed and task orientated according to individual need. The group acknowledged and agreed with the Stroke Quality Standard [189] which defines rehabilitation therapy as physiotherapy, occupational therapy and speech and language therapy with other treatments as required delivered in either a hospital or community setting. Each therapy is provided through face to face contact either individually or as part of a group treatment and does not include administrative tasks related to patients. This should be offered to all who have the physical and mental ability to participate and who demonstrate through their individual goals that they continue to benefit from the therapy. The GDG agreed it was important that people should be able to re-access rehabilitation at any stage of the stroke pathway when needed.

7 Support and information

7.1 Providing support and information

Provision of appropriate, accurate and timely information is a key component of post-stroke care. It is a core recommendation of many policy documents, such as the National Stroke Strategy[61]. Despite this, many research reports indicate that patients and their families feel their information needs have been poorly met. However information provision is a nebulous concept and it is difficult to determine an appropriate objective outcome. It is acknowledged that information is commonly passively available through leaflets. The GDG sought to identify effective active methods of information provision which would provide positive benefits in terms of mood and activities of daily living.

7.1.1 Evidence review: What is the clinical and cost-effectiveness of supported information provision versus unsupported information provision on mood and depression in people with stroke?

Clinical Methodological Introduction	
Population:	Adults and young people 16 or older who have had a stroke
Intervention:	Supported information giving (active information provision, encourage feedback, peer support, interactive computer programme)
Comparison:	Unsupported Information (such as, leaflets and notice board information)
Outcomes:	Impact on mood/depression: • Hospital Anxiety and Depression Scale • General Health Questionnaire • Visual Analogue Mood Scale • Stroke Aphasic Depression Questionnaire (SAD-Q) • Geriatric Depression Scale • Beck Depression Inventory • Self-efficacy • General Self-efficacy Scale • Stroke Self-efficacy Questionnaire • Locus of Control Scale • Extended activities of daily living • Nottingham extended activities of daily living • Frenchay Activities Index • Yale mood scale

7.1.1.1 Clinical evidence

Searches were conducted for systematic reviews and RCTs comparing interventions of supported information with unsupported information for adults or young people of 16 years old after stroke. Only studies with a minimum sample size of 20 participants (10 in each arm) were selected. Five (5) RCTs were identified.

Table 38 summarises the population, intervention, comparison and outcomes for each of the studies.

Table 38: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix H.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Ellis, 2005[75]	Patients with stroke in the previous 3 months with no severe cognitive impairments.	Additional input from the Stroke Nurse Specialist (SNS), who reviewed patients at monthly intervals for approximately 3 months. Individual advice on lifestyle changes, the importance of medication compliance and its relevance to secondary prevention was given. (N=94)	Usual care, which included generic risk factor advice from medical staff as well as the SNS, given within the outpatient context. Following enrolment the control group had no further input from the SNS. (N=98)	• Geriatric Depression Scale
Hoffmann, 2007[112]	Patients with stroke (mean 8.4 days post onset) who had a reported English-proficiency level; corrected hearing and vision; no reported or observable dementia and were medically stable.	Computer-generated tailored written information designed so that the health professional providing the intervention (in this trial, the research nurse) communicates and collaborates with the patient to establish his or her information needs. (N=69)	Generic written information; a series of three stroke fact sheets produced by the Stroke Association of Queensland which covered topics such as how stroke occurs, risk factors, and physical, cognitive and emotional changes following a stroke. (N=69)	• Self-efficacy • Hospital Anxiety and Depression Scale
Lowe, 2007[159]	Patients with a primary diagnosis of acute stroke, without severe cognitive or communication problems	CareFile project (an individualised information booklet) in addition to usual care.(N=50)	Usual care, including Stroke Association information leaflets and follow-up in Stroke Review Clinic. (N=50)	• Mood (Yale single question)
Rodgers, 1999[218]	Medically stable patients (5 and 9 days post onset). No further details provided.	Multidisciplinary Stroke Education Program (SEP) consisting of a rolling program of one 1-hour small group educational sessions for inpatients and their informal carer followed by six 1-hour educational sessions after discharge from hospital. (N=121)	Information leaflet (on a number of topics) and routine communication with nurses, doctors and therapy staff members throughout inpatient stay. (N=83)	• Hospital Anxiety and Depression Scale • Nottingham Extended Activities of Daily Living
Smith, 2004[243]	Patients with a diagnosis of	Specifically designed stroke information	Usual practice: members of the	• Frenchay Activities Index.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
	acute stroke; no receptive aphasia; no cognitive impairment and proficient in English.	(Stroke Recovery Programme) manual and patients were invited to attend education meetings every two weeks with members of their multidisciplinary team. (N=84)	stroke unit multidisciplinary team were free to discuss aspects of treatment and respond to any specific queries. (N=86)	• Hospital Anxiety and Depression Scale

Comparison: Supported information versus unsupported information

Table 39: Supported information versus unsupported information- clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Supported information Mean (SD) Median (IQR)/ Frequency (%)/	Unsupported information Mean (SD) Median (IQR)/ Frequency (%)/	Mean Difference /Risk Ratio (95% CI)	Absolute effect / Mean Difference (MD) (95% CI) or P value	Confidence (in effect)
Geriatric Depression Score (5 months follow-up) (Better indicated by lower values)										
Ellis, 2005[75]	RCT- Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (a)	4.3 (3.17)	5.1 (3.24)	-0.80 (-1.71, 0.11)	MD 0.8 lower (1.71 lower to 0.11 higher)	Moderate
Self-efficacy (to get information about the disease) (3 months follow-up) (Better indicated by higher values)										
Hoffmann, 2007[112]	RCT- Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (a)	0.2	0.7	-0.50 (-1.39, 0.39)	MD 0.5 lower (1.39 lower to 0.39 higher)	Moderate
Self-efficacy (to obtain help from family, community, and friends) (3 months follow-up) (Better indicated by higher values)										
Hoffmann, 2007[112]	RCT- Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (a)	0.0	0.2	-0.20 (-0.59, 0.19)	MD 0.2 lower (0.59 lower to 0.19 higher)	Moderate
Self-efficacy (to communicate with the doctor) (3 months follow-up) (Better indicated by higher values)										
Hoffmann, 2007[112]	RCT- Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (a)	0.3	-0.1	0.40 (-0.21, 1.01)	MD 0.4 higher (0.21 lower to	Moderate

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Supported information Mean (SD) Median (IQR)/ Frequency (%)/	Unsupported information Mean (SD) Median (IQR)/ Frequency (%)/	Mean Difference /Risk Ratio (95% CI)	Absolute effect / Mean Difference (MD) (95% CI) or P value	Confidence (in effect)
									1.01 higher)	
Self-efficacy (to control/manage depression) (3 months follow-up) (Better indicated by higher values)										
Hoffmann, 2007[112]	RCT- Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (a)	0.0	0.3	-0.30 (-0.83, 0.23)	MD 0.3 lower (0.83 lower to 0.23 higher)	Moderate
Self-efficacy (to manage the disease in general) (3 months follow-up) (Better indicated by higher values)										
Hoffmann, 2007[112]	RCT- Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	No serious imprecision	0.4	0.3	0.10 (-0.18, 0.38)	MD 0.1 higher (0.18 lower to 0.38 higher)	High
Self-efficacy (to manage symptoms) (3 months follow-up) (Better indicated by higher values)										
Hoffmann, 2007[112]	RCT- Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Very serious imprecision (b)	0.0	-0.2	0.2 (-0.64 to 1.04)	MD 0.2 higher (0.64 lower to 1.04 higher)	Low
Anxiety (Hospital Anxiety and Depression Scale) (3 months follow-up) (Better indicated by lower values)										
Hoffmann, 2007[112]	RCT- Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (a)	-0.1	-1.5	1.40 (0.14, 2.66)	MD 1.40 higher (0.14 to 2.66 higher)	Moderate
Anxiety (score in Hospital and Anxiety Depression Scale>=11) (3 months follow-up) (Better indicated by lower values)										

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Supported information Mean (SD) Median (IQR)/ Frequency (%)/	Unsupported information Mean (SD) Median (IQR)/ Frequency (%)/	Mean Difference /Risk Ratio (95% CI)	Absolute effect / Mean Difference (MD) (95% CI) or P value	Confidence (in effect)
Smith, 2004[243]	RCT- Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (c)	5/49 (10.2%)	11/45 (24.4%)	RR 0.42 (0.16 to 1.11)	142 fewer per 1000 (from 205 fewer to 27 more)	Moderate
Anxiety (score in Hospital Anxiety and Depression Scale>=11) (6 months follow-up) (Better indicated by lower values)										
Rodgers, 1999[218], Smith, 2004[243]	RCT- Single blinded	No serious limitations	No serious inconsistency	No serious inconsistency	Serious imprecision (c)	44/140 (31.4%)	43/107 (40.2%)	RR 0.76 (0.55 to 1.06)	96 fewer per 1000 (from 181 fewer to 24 more)	Moderate
Depression (Hospital Anxiety Depression Scale) (3 months follow-up) (Better indicated by higher values)										
Hoffmann, 2007[112]	RCT- Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Very serious imprecision (b)	0.4	0.3	0.1 (-1.46 to 1.66)	MD 0.1 higher (1.46 lower to 1.66 higher)	Low
Mood (Yale Scale) (6 months follow-up) (Better indicated by higher values)										
Lowe, 2007[159]	RCT- Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (c)	31/44 (70.5%)	26/40 (65%)	RR 1.08 (0.81 to 1.46)	52 more per 1000 (from 123 fewer to 299 more)	Moderate
Depression (score in Hospital Anxiety Depression Scale>=11) (3 months follow-up) (Better indicated by lower values)										

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Supported information Mean (SD) Median (IQR)/ Frequency (%)/	Unsupported information Mean (SD) Median (IQR)/ Frequency (%)/	Mean Difference /Risk Ratio (95% CI)	Absolute effect / Mean Difference (MD) (95% CI) or P value	Confidence (in effect)
Smith, 2004[243]	RCT- Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Very serious imprecision (d)	5/49 (10.2%)	9/45 (20%)	RR 0.51 (0.18 to 1.41)	98 fewer per 1000 (from 164 fewer to 82 more)	Low
Depression (score in Hospital Anxiety Depression Scale>=11) (6 months follow-up) (Better indicated by lower values)										
Rodgers, 1999[218], Smith, 2004[243]	RCT- Single blinded	No serious limitations	No serious inconsistency	No serious inconsistency	Serious imprecision (c)	35/140 (25%)	34/107 (31.8%)	RR 0.76 (0.51 to 1.14)	76 fewer per 1000 (from 156 fewer to 44 more)	Moderate
Nottingham Extended Activities of Daily Living (6 months follow-up) (Better indicated by higher values)										
Rodgers, 1999[218]	RCT- Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	(e)	7 (0-22)	8 (0-21)	(f)	0.69(h)	Moderate (e)
Frenchay Activities Index (3 months follow-up) (Better indicated by higher values)										
Smith, 2004[243]	RCT- Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	(e)	1 (0-30)	0 (0-23)	(f)	(f)	High (e)
Frenchay Activities Index (6 months follow-up) (Better indicated by higher values)										
Smith, 2004[243]	RCT- Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	(e)	5 (0-32)	3 (0-33)	(f)	(f)	High (e)

[(a)] Confidence interval crosses one end of default MID.
[(b)] Confidence interval crosses both ends of default MID.
[(c)] Confidence interval crosses one end of default MID.
[(d)] Confidence interval crosses both ends of default MID.
[(e)] Imprecision could not be assessed because only median and interquartile ranges of data reported.
[(f)] Relative and absolute effect could not be assessed because median and interquartile ranges of data reported.

7.1.1.2 Economic evidence

Literature review

No relevant economic evaluations comparing supported information provision with usual care were identified.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

The studies included in the clinical review used different interventions. Typical unit costs relevant to the interventions in the studies included in the clinical review were reviewed by the GDG in conjunction with the study intervention descriptions to aid consideration of cost effectiveness. The study interventions are described in full in **Table 38**. Estimated unit costs[h] for relevant personnel are listed below.

- A multi-disciplinary stroke education program was described by Rodgers, 1999[218] consisting of one 1-hour group session and six 1-hour sessions post-discharge. Each session was led by a member of the team. The usual care comparator included routine communication with healthcare professionals and a telephone hotline number.
  - District nurse (band 6) – £51 per hour spent with a patient
  - Clinical psychologist (band 8a) - £136 per hour of client contact
  - Speech and language therapist (band 6) – £47 per hour of client contact
  - Occupational therapist (band 6) – £45 per hour of client contact
  - Physiotherapist (band 6) – £48 (community) and £45 (hospital) per hour of client contact
  - Social worker – £54 per hour of client-related work
- Ellis, 2005[75] looked at an intervention provided by a Stroke Nurse Specialist. The patients were reviewed monthly for 3 months. This intervention was additional to usual care.
  - Nurse specialist (band 7– nurse advanced) - £81 per hour of client contact.
- Lowe, 2007[159] assessed the provision of information booklets to patients. The booklet included general information about stroke as well as sections were patient specific information could be entered. A discussion (15-20 minutes) about the content of the booklet was held with patients by a member of the multidisciplinary team prior to discharge – see relevant unit costs above. This intervention was additional to usual care.
- Computer-generated tailored information was provided to patients in the study by Hoffman, 2007. Patients were able to select the type and amount of information from a range of topics [112]. A research nurse also elaborated on the topics and placed the booklet (generated from Microsoft Word) in personalised folders. This intervention was additional to usual care.
  - Nurse (band 6 – nurse specialist) - £43 per hour of patient contact.
  - A licence for the 'What you need to know about stroke' education package computer program[40] developed by the University of Queensland, Australia costs £86(excluding VAT)[i]

h Estimated based on data and methods from Personal Social Services Research Unit 'Unit costs of health and social care' report and relevant Agenda for Change salary bands[50] (typical salary band identified by clinical GDG members).

i AU$199(2011) converted to UK pounds (2010) using purchasing power parities[194].

- Patients were given a stroke recovery manual and invited to attend education meetings every two weeks in the study by Smith, 2004[243]. The manual contained information about stroke, agreed goals as discussed at the meetings as well as a section for carers. The meetings (approximately 20 minutes) were with a multidisciplinary team (doctor, nurse, physiotherapist and occupational therapist). In usual care comparator arm information leaflets were freely available and staff responded to specific questions.
  - Medical consultant - £132 per contract hour
  - Unit costs for other team members are as listed above.

Evidence statements

Clinical evidence statements

One study[75]comprising 192 participants found no significant difference in depression at 5 months after stroke between the group that received supported information and the group that received unsupported information (MODERATE CONFIDENCE IN EFFECT).

One study[112] comprising 138 participants found no significant difference between the group that received supported information and the group that received unsupported information at 3 months after stroke in self-efficacy with the following sections:

- Getting information about the disease (MODERATE CONFIDENCE IN EFFECT)
- Obtaining help from family, community, and friends (LOW CONFIDENCE IN EFFECT)
- Communicating with the doctor (MODERATE CONFIDENCE IN EFFECT)
- Controlling/managing depression (MODERATE CONFIDENCE IN EFFECT)
- Managing the disease in general (HIGH CONFIDENCE IN EFFECT)
- Managing symptoms (LOW CONFIDENCE IN EFFECT)

One study[112] comprising 138 participants showed significant improvement in anxiety at 3 months after stroke with the group that received unsupported information compared to the group that received supported information (MODERATE CONFIDENCE IN EFFECT)

One study[243] comprising 170 participants found no significant difference in the proportion of participants experienced anxiety at 3 months after stroke between the group that received supported information and the unsupported information group (MODERATE CONFIDENCE IN EFFECT).

Two studies[218,243]comprising 374 participants found no significant difference in anxiety at 6 months after stroke between the group that received supported information and the unsupported information group (MODERATE CONFIDENCE IN EFFECT).

One study[112] comprising 138 participants found no significant difference in depression at 3 months after stroke with the group that received supported information and the group that received unsupported information (LOW CONFIDENCE IN EFFECT)

One study[243] comprising 170 participants found no significant difference in in the proportion of participants experienced depression at 3 months after stroke between the group that received supported information and the unsupported information group (VERY LOW CONFIDENCE IN EFFECT).

One study[159] comprising 100 participants found no significant difference in mood at 6 months after stroke between the group that received supported information and the unsupported information group (MODERATE CONFIDENCE IN EFFECT).

Two studies[218,243]comprising 374 participants found no significant difference in depression at 6 months after stroke between the group that received supported information and the unsupported information group (MODERATE CONFIDENCE IN EFFECT).

Economic evidence statements

No cost effectiveness evidence was identified.

7.1.2 Recommendations and link to evidence

Recommendations	**36. Working with the person with stroke and their family or carer, identify their information needs and how to deliver them, taking into account specific impairments such as aphasia and cognitive impairments. Pace the information to the person's emotional adjustment.** **37. Provide information about local resources (for example, leisure, housing, social services and the voluntary sector) that can help to support the needs and priorities of the person with stroke and their family or carer.** **38. Review information needs at the person's 6-month and annual stroke reviews and at the start and completion of any intervention period.** **39. NICE has produced guidance on the components of good patient experience in adult NHS services. Follow the recommendations in Patient experience in adult NHS services (NICE clinical guideline 138)[j].**
Relative values of different outcomes	It is difficult to identify and capture the different outputs of information provision. A range of potential outputs include: a better understanding of stroke, changes in behaviour (for example compliance with medication, increased satisfaction with services, decreased anxiety and depression, increased activity and participation in social roles after stroke). The GDG considered that the relationship between information provision and the outputs are unlikely to be linear and will be moderated by a large range of factors including: personal factors (patients' educational levels, pre-morbid mental health status), disease factors (such as cognitive factors and aphasia), and social factors (such as family beliefs). The timing and pacing of information to patients' needs is also critical. Patient groups repeatedly ask for more information and therefore factors to be considered are what information is required, the appropriate method of delivery for the patient and the timeliness of provision.
Trade-off between clinical benefits and harms	On the basis of these studies it appears that additional supported information provision does not affect improvement in mood. The baseline scores were such that the majority of the patients were not depressed and the change scores were not clinically significant.

[j] For recommendations on continuity of care and relationships see section 1.4 and for recommendations on enabling patients to actively participate in their care see section 1.5.

	The GDG noted that standard information briefing may not be relevant; and that perhaps guiding patients toward articulating what information they need would be of more benefit to patients.
Economic considerations	Supported information provision may have a resource impact over usual care but this would vary depending on the specific intervention, and on the patient's needs. The clinical studies reviewed did not provide evidence that patient health outcomes were improved; however, as noted above, the GDG considered that the benefits of information provision were hard to measure and there may be additional aims and benefits of information giving valued by patients but not captured by these outcomes.
Quality of evidence	The GDG thought that the patients' perceptions and attributions are informed by a wide range of sources, much of which is available inside and outside of the health care environment. The included studies examined the added value of a more structured approach to information provision provided by health care professionals. The studies are necessarily reductionist in a complex environment. The components of the interventions were inadequately described and the evidence was generally of high to low quality for the outcomes assessed due to imprecision of the effect estimate. There was consensus that provision of information was useful**.** There was very little consensus on how and when this should be done, something that is reflected in the study designs. The GDG noted that the study by Ellis [75] was focused on assessing the role of the nurse specialist rather than the intervention. The Hoffman study [112] included only English speakers and therefore it did not reflect clinical practice.
Other considerations	The GDG agreed that information provided is likely to vary from patient to patient and needs to reflect patients' needs and priorities, family expectations, and the local resources provided by leisure, housing, social services and the voluntary sector to support these. Information needs are likely to vary at different stages after stroke. The GDG noted that specific groups such as those with dysphasia or cognitive impairments may have particular information needs.

8 Cognitive functioning

Following stroke, many people experience difficulties in arousal, attention, concentration, memory, perception, problem solving, decision making, insight and other areas of cognition that impede their ability to function in everyday activities. Cognitive abilities and disabilities must be considered in addressing all areas of functioning including communication, mobility, self-care, social interaction, recreational pursuits, and other productive activities such as school or work.

Cognitive rehabilitation can be conceptualised in two ways. It can be designed to facilitate restoration of or compensation for underlying impairment(s) with the aim of improving functional performance. Often both restorative and compensatory approaches are integrated in order to maximise function. These interventions should be based on the nature and scope of neuropsychological impairments identified on neuropsychological assessments using validated standardised tests, and an assessment of the impact of these impairments on function.

In practical terms, attention, memory, spatial awareness, apraxia and perception are critical to successful rehabilitation in many other domains. However, this chapter of the guideline focuses on visual neglect, memory and attention.

For the review of psychological therapies in relation to emotional functioning for people after stroke please see chapter 9

8.1 Visual neglect

The most striking feature of neglect is an inability of the patient to orient towards and attend to stimuli – even their own body parts – in the contralesional space (the left side for patients with right hemisphere lesions) [1 2], despite an ability to make such exploratory movements when prompted. The severity of the inattention may vary according to context. In circumstances where patients are also unaware of their deficit (anosognosia), the disorder becomes a particularly difficult syndrome to rehabilitate [3]. Persistent neglect is often associated with poor functional outcome [4], impacting on everyday tasks such as dressing, feeding and reading.

Neglect is difficult to treat in clinical practice. This difficulty can be attributed to the fact that it is a syndrome and does not seem to be due to a disruption of just one cognitive process but rather due to different combinations of neuropsychological deficits [4]. It is, therefore, unlikely that a single therapeutic intervention will suit all individuals.

Neglect can present in different modalities for example, sensory, motor or visual. Unilateral visual neglect is a relatively common problem particularly following hemispheric stroke. Approaches to treatment include both restorative and compensatory approaches, including the use of goggles with prisms that induce a rightward optical shift of ~5–15° has been tried. The induced optical shift initially leads to errors of pointing to the right of the visual target, leading in turn to compensatory leftward manual corrections. In patients, this compensatory behaviour is typically followed by an 'after effect' when the prisms are removed with manual errors now being biased towards the left instead.

8.1.1 Evidence review: In people after stroke what is the clinical and cost-effectiveness of cognitive rehabilitation versus usual care to improve spatial awareness and/or visual neglect?

Clinical Methodological Introduction	
Population:	Adults and young people 16 or older who have had a stroke.
Intervention:	• Prisms, eye patches and goggles,

Clinical Methodological Introduction	
	• Track to left, • Approaches such as cube copying.
Comparison:	Usual Care
Outcomes:	• Behavioural Inattention Test (BIT), • Drawing tests (clock drawing etc.), • Line Bisection tests, • All cancellation tests (line cancellation, bell cancellation etc.), • Sentence reading, • Target screen examinations (lump together all cancellation tests and drawing tests), • Rivermead Perceptual Assessment Battery (RPAB)

8.1.1.1 Clinical evidence

Searches were conducted for systematic reviews and RCTs comparing the clinical effectiveness of cognitive rehabilitation therapies with usual care to improve spatial awareness and/or visual neglect for adults and young people 16 or older who have had a stroke. Only studies with a minimum sample size of 10 participants (5 in each arm) were selected. Nine (9) RCTs were identified which addressed visual neglect. **Table 40** summarises the population, intervention and outcomes for each of the studies.

Table 40: Summary of studies of included in the clinical evidence review. For full details of the extraction please see Appendix F.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Fanthome, 1995[80]	Patients with a previous stroke affecting the right side of the body; under 80 years of age with no history of dementia or psychiatric problems. All patients were in hospital and receiving physiotherapy and occupational therapy but no previous treatment for their visual neglect.	Wearing the eye movement detection glasses which provided a reminder bleep if patients failed to move their eyes to the left for 15 seconds for 2 hours and 40 minutes/ week for 4 weeks. (N=9)	No treatment was provided for their visual inattention or other perceptual deficits for 4 weeks. (N=9)	• BIT conventional subset • BIT behavioural subset.
Kalra, 1997[130]	Acute stroke patients (the median duration between the acute episode and randomization was 6 days (range 2- 14 days). Patients with visual neglect were identified by comprehensive multidisciplinary assessments (including line bisection test).	Modified approach to conventional therapy involving spatiomotor cueing based on the "attentional-motor integration" model and early emphasis on restoration of function. (N=25)	Conventional therapy input concentrating on restoration of normal tone, movement patterns and motor activity before addressing skilled functional activity. (N=25)	• Rivermead Perceptual Assessment Battery (RPAB) • RPAB cancellation subtest • RPAB body image subtest.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Nys, 2008[191]	Patients with stroke and visual neglect as assessed by the BIT. Patients who performed below the cut-off on at least two of the four subtasks of the BIT were included in the study.	Four-day-in-a-row experimental treatment with 10 degree rightward deviating prisms. (N=10)	Four-day-in-a-row experimental treatment without prism. (N=6)	• Line bisection test • Star cancellation test • Representational drawing test, • BIT (total score).
Robertson, 1990[215]	Patients with significant unilateral left field visual neglect according to BIT and defined as failure in 3 out of 9 tests.	Computerised scanning and attention training, 14 sessions of 75 minutes each usually 2 times/week. (N=20)	Exposure to plausible computer activities that were considered not to improve cognitive function wogames, quizzes and simple logical games such as 'reds and greens' for an average of 11.4 hours (SD 5.2) (N=16)	• BIT (total score) • Letter cancellation test.
Robertson, 2002[216]	Patients with diagnosis of right hemispheric stroke and unilateral visual neglect (as defined by a score of 51 or less on the star cancellation test of the BIT or a score of 7 or less on the line bisection test). Participants had no other existing comorbidities that prevent or influence the assessment.	Perceptual training plus limb activating device provided in 12 sessions of 45 minutes duration over a 12 week period. (N=19)	Perceptual training plus "dummy" (inactive) limb activating device provided in 12 sessions of 45 minutes duration over a 12 week period. (N=21)	• BIT Behavioural subset • Letter cancellation test.
Rossi, 1990[222]	Patients with stroke and homonymous hemianopia or unilateral visual neglect.	15-diopter plastic press-on fresnel prisms plus receiving routine rehabilitation programme (physical, occupational speech therapy). (N=18)	No prism but receiving routine rehabilitation programme (physical, occupational speech therapy) (N=21)	• Line bisection test • Line cancellation test task • Tangent Screen Examination.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Tsang, 2009[263]	Participants were inpatients with sub acute stroke (mean time since stroke 3 wks.) with left visual neglect based on the total score on the BIT.	4 weeks of conventional occupational therapy with right half-field eye patching glasses, which were worn throughout the occupational therapy treatment sessions. Five occupational therapy sessions of 60 minutes each session/ week.(N=17)	4 weeks of conventional occupational therapy without eye-patching. Five occupational therapy sessions of 60 minutes each session/week. (N=17)	• BIT Conventional subset.
Turton 2010[264]	Right hemispheric first time stroke patients (at least 20 days post stroke) with unilateral spatial neglect	Participants were instructed to perform repeated pointing movements to targets, using the right "unaffected" hand while wearing the prism glasses (using 10 dioptre, 6 degree prisms) each weekday for 2 weeks. Before wearing the glasses, participants were given some pointing practice, with vision of the terminal point of movement, to ensure they understood the task (N=17)	Sham treatment using plain glasses every day during the week for 2 weeks. Participants were given the same pointing practice, with vision of the terminal point of movement as the intervention group. (N=19)	• BIT Conventional subset
Mancuso 2012[166]	Outpatients with left visual neglect resulting from right hemisphere vascular lesion. All patients were selected in accordance with tests for neglect who had very low scores on at least two (out of how many is a bit unclear) visual neglect tests.	Participants carried out a pointing exercise whilst wearing prismatic lenses producing optical shift of 5 degrees to the right. There were overall five rehabilitation sessions lasting about 30 minutes each for one week.	Participants received the same pointing exercise whilst wearing neutral lenses.	• Line cancellation tests • Bells cancellation tests • Lines orientation test • Fours subtests of BIT (line bisection, copying drawings, finding objects and dealing playing cards tests)

Comparison: Cognitive rehabilitation for spatial awareness and/or visual neglect versus usual care

Table 41: Cognitive rehabilitation for spatial awareness and/or visual neglect versus usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
						Cognitive rehabilitation	Usual care	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Frequency (%)/ mean (SD)/ median (range)	Frequency (%)/ mean (SD) / median (range)	Mean difference/ Risk Ratio (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
BIT (total score) (post-treatment effect) (Better indicated by higher values)										
1 Robertson 1990 [215]	RCT – single blind	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision (b)	52 (24)	59.9 (20.2)	-7.9 (-22.34, 6.54)	MD 7.9 lower (22.34 lower to 6.54 higher)	Low
BIT (total score) (6 months follow-up) (Better indicated by higher values)										
2 Nys 2008 [191] Robertson 1990 [215]	RCTs – single blind	Serious limitations (c)	No serious inconsistency	No serious indirectness	Serious imprecision (b)	Nys 60.2 (21.9) Robertson 60.1 (18.6)	Nys 61.2 (21.2) Robertson 61.8 (21.5)	-1.51 (-12.86, 9.85)	MD 1.51 lower (12.86 lower to 9.85 higher)	Low
BIT conventional (post-treatment effect) (Better indicated by higher values)										
2 Fanthome 1995[80] Turton 2010[264]	RCTs – single blinded	Serious limitations (d)	No serious inconsistency	No serious indirectness	Very serious imprecision (e,f)	Fanthome 93.4 (41.3) Turton 14.8 (18.8)	Fanthome 90.2 (48.4) Turton 9.7 (15.9)	4.97 (-6.07, 16.00)	MD 4.97 higher (6.077 lower to 16.00	Very low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cognitive rehabilitation Frequency (%)/ mean (SD)/ median (range)	Usual care Frequency (%)/ mean (SD) / median (range)	Mean difference/ Risk Ratio (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
									higher)	
BIT conventional (1-2 months follow-up) (Better indicated by higher values)										
3 Fanthome 1995[80] Nys 2008[191] Turton 2010[264]	RCTs – single blinded	Serious limitations (d)	No serious inconsistency	No serious indirectness	Serious imprecision (b)	Fanthome 97.6 (27.9) Nys 123.2 (25.1) Turton 24.5 (15.7)	Fanthome 84 (50.3) Nys 116.5 (36.5) Turton 21.8 (22.2)	4.11 (-7.03, 15.25)	MD 4.11 higher (7.03 lower to 15.25 higher)	Low
BIT behavioural (post-treatment effect) (Better indicated by higher values)										
2 Fanthome 1995[80] Robertson 2002[216]	RCTs – single blinded	Serious limitations (d)	No serious inconsistency	No serious indirectness	No serious imprecision	Fanthome 37.6 (21.3) Robertson 30.2 (11.9)	Fanthome 42.9 (29.3) Robertson 31.2 (11.9)	-1.38 (-8.43, 5.67)	MD 1.38 lower (8.43 lower to 5.67 higher)	Moderate
BIT behavioural (2-3 months follow-up) (Better indicated by higher values)										
2 Fanthome 1995[80] Robertson 2002[216]	RCTs – single blinded	Serious limitations (d)	No serious inconsistency	No serious indirectness	No serious imprecision	Fanthome 45.1 (19) Robertson 30.1 (11.5)	Fanthome 39 (26) Robertson 32.8 (11.9)	-1.76 (-8.62, 5.09)	MD 1.76 lower (8.62 lower to 5.09 higher)	Moderate
BIT behavioural (6 months follow-up) (Better indicated by higher values)										
1	RCT –	Very serious	No serious	No serious	Serious	30.1 (13.2)	33.5 (12.6)	-3.40 (	MD 3.4	Very low

Quality assessment						Summary of findings				
						Cognitive rehabilitation Frequency (%)/ mean (SD)/ median (range)	Usual care Frequency (%)/ mean (SD) / median (range)	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision			Mean difference/ Risk Ratio (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
Robertson 2002[216]	single blinded	limitations (g,h)	inconsistency	indirectness	imprecision (b)			-11.42, 4.62)	lower (11.42 lower to 4.62 higher)	
Line bisection (post-treatment effect) (Better indicated by higher values)										
2 Nys 2008[191] Tsang 2009[263]	RCT – single blinded	Serious limitations (i)	No serious inconsistency	No serious indirectness	Serious imprecision (b)	Nys 2.6 (2.8) Tsang -0.76 (1.6)	Nys 2.5 (2.5) Tsang -0.02 (2.46)	-0.56 (-1.79, 0.68)	MD 0.56 lower (1.79 lower to 0.68 higher)	Low
Line bisection test (1 month follow-up) (Better indicated by higher values)										
2 Nys 2008[191] Rossi 1990	RCTs – single blinded/ unblinded	Very serious limitations (j)	No serious inconsistency	No serious indirectness	No serious imprecision	Nys 6.1 (3.4) Rossi 0.68 (0.85)	Nys 5.2 (3.1) Rossi 2.2 (2.29)	-1.29 (-2.29, -0.29)	MD 1.29 (2.29 to 0.29 lower)	Low
Star Cancellation test (post-treatment effect) (Better indicated by higher values)										
2 Nys 2008[191] Tsang 2009[263]	RCTs – single blinded	Serious limitations (i)	No serious inconsistency	No serious indirectness	Serious imprecision (b)	Nys 21.5 (13.1) Tsang 8.65 (13.15)	Nys 20.7 (19) Tsang 1.88 (5.02)	5.99 (-0.25, 12.23)	MD 5.99 higher (0.25 lower to 12.23 higher)	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cognitive rehabilitation Frequency (%)/ mean (SD)/ median (range)	Usual care Frequency (%)/ mean (SD) / median (range)	Mean difference/ Risk Ratio (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
Star Cancellation test (1 month follow-up) (Better indicated by higher values)										
1 Nys 2008[191]	RCT – single blinded	Serious limitations (k)	No serious inconsistency	No serious indirectness	Very serious imprecision (e,f)	43.1 (13.7)	42.3 (16.4)	0.80 (-14.83, 16.43)	MD 0.8 higher (14.83 lower to 16.43 higher)	Very low
RPAB (total score) (post-treatment effect) (Better indicated by higher values)										
1 Kalra 1997[130]	RCT – single blinded	Serious limitations (k)	No serious inconsistency	No serious indirectness	Serious imprecision (b)	224.32 (55.38)	199.44 (64.87)	24.88 (-8.55, 58.31)	MD 24.88 higher (8.55 lower to 58.31 higher)	Low
RPAB (cancellation subtest) (post-treatment effect) (Better indicated by higher values)										
1 Kalra 1997[130]	RCTs – single blinded	Serious limitations (k)	No serious inconsistency	No serious indirectness	Serious imprecision (b)	Kalra 37.19 (13.1)	Kalra 30.12 (18.45)	7.07 (-1.80 - 15.94)	MD 7.07 higher (1.80 lower to 15.94 higher)	Low
RPAB (body image subtest) (post-treatment effect) (Better indicated by higher values)										
1 Kalra 1997[130]	RCTs – single blinded	Serious limitations (k)	No serious inconsistency	No serious indirectness	No serious imprecision	13.19 (1.47)	9.72 (1.33)	3.47 (2.69, 4.25)	MD 3.47 higher (2.69 to	Moderate

Quality assessment						Summary of findings				
						Cognitive rehabilitation Frequency (%)/ mean (SD)/ median (range)	Usual care Frequency (%)/ mean (SD) / median (range)	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision			Mean difference/ Risk Ratio (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
									4.25 higher)	
Letter cancellation test (post-treatment effect) (Better indicated by higher values)										
2 Robertson 1990[215] Tsang 2009[263]	RCTs – single blinded	Serious limitations (c)	No serious inconsistency	No serious indirectness	No serious imprecision	Robertson 43.4 (30.4) Tsang 10 (12.12)	Robertson 43.2 (28.3) Tsang 2.65 (6.52)	6.61 (0.41, 12.80)	MD 6.61 higher (0.41 to 12.80 higher	Moderate
Letter Cancellation test (6 months follow-up) (Better indicated by higher values)										
1 Robertson 1990[215]	RCT – single blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision (b)	20 (16.4)	23.1 (14.5)	-3.10 (-13.21, 7.01)	MD 3.10 lower (13.21 lower to 7.01 higher)	Low
Tangent screen examination (post-treatment effect) (Better indicated by higher values)										
1 Rossi 1990[222]	RCT – unblinded	Very serious limitations (o)	No serious inconsistency	No serious indirectness	No serious imprecision	15/18 (83.3%)	7/21 (33.3%)	RR 2.50 (1.32 to 4.74)	500 more per 1000 (from 185 more to 625 more)	Low
Line Cancellation test (post-treatment effect) (Better indicated by higher values)										
1 Rossi 1990[222]	RCT – unblinded	Very serious limitations (o)	No serious inconsistency	No serious indirectness	No serious imprecision	2.4 (4.24)	9.8 (9.17)	-7.40 (-11.78, -3.02)	MD 7.4 lower (11.78 to	Low

Quality assessment						Summary of findings				
						Cognitive rehabilitation Frequency (%)/ mean (SD)/ median (range)	Usual care Frequency (%)/ mean (SD) / median (range)	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision			Mean difference/ Risk Ratio (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
									3.02 lower)	
Representational drawing test (post-treatment effect) (Better indicated by higher values)										
2 Nys 2008[191] Tsang 2009[263]	RCTs – single blinded	Serious limitations (i)	No serious inconsistency	No serious indirectness	Very serious imprecision (p)	Nys 0.8 (0.8) Tsang 0.18 (1.19)	Nys 1 (0.9) Tsang 0.18 (0.88)	-0.08 (-0.63, 0.47)	MD 0.08 lower (0.63 lower to 0.47 higher)	Very low
Representational drawing test (1 month follow-up) (Better indicated by higher values)										
1 Nys 2008[191]	RCT – single blinded	Serious limitations (k)	No serious inconsistency	No serious indirectness	Serious imprecision (b,e)	1.6 (1)	2.3 (0.5)	-0.70 (-1.44, 0.04)	MD 0.7 lower (1.44 lower to 0.04 higher)	Low

[a] Partial randomization and unclear allocation concealment
[b] Confidence interval crossed one end of default MID.
[c] One had partial randomization (Robertson, 1990), one study had unclear randomization (Nys, 2008) and both studies had unclear allocation concealment.
[d] Unclear randomization process and allocation concealment.
[e] Small sample size, either arm <10 participants (Nys 2008; Fanthome 1995).
[f] Confidence interval crossed both ends of default MID.
[g] Unclear randomization and allocation concealment.
[h] Drop-out rate ≥20% in each arm (Robertson 2002).
[i] Unclear randomization and allocation concealment (Nys, 2008)
[j] Unblinded (Rossi 1990) with unclear randomization and allocation concealment.
[k] Unclear randomization and allocation concealment.
[l] Inadequate randomization and unclear allocation concealment.

[m] Imprecision could not be assessed as results were presented only in medians (range).
[n] No mean or standard deviation was reported in the study, so could not be meta-analysed and unable to calculate relative and absolute effect.
[o] Unblinded study with unclear randomization and allocation concealment (Rossi 1990).
[p] Confidence interval crossed both ends of default MID.

Narrative summary

The following studies are summarised as a narrative because the results were not presented in numerical data that could be included in the GRADE table:

One randomised control study[166] comprising 29 participants, who had tested positive for visual neglect, reported improvements for both the experimental (prismatic lenses of 5 degrees plus pointing task) and control group (sham lenses plus pointing task). However, participants wearing prismatic lenses did not improve significantly more than the control participants (VERY LOW CONFIDENCE IN EFFECT).

8.1.1.2 Economic evidence

Literature review

No relevant economic evaluations comparing cognitive rehabilitation interventions with usual care to improve spatial awareness and/or visual neglect were identified.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

The studies identified in the clinical review used a variety of different interventions. The GDG considered that a typical cost could be estimated based on the resources reported in the RCT by Turton et al (2010)[264] that looked at using prism glasses in ten sessions with an occupational therapist. The author was contacted for information on resources used in the trial. In the trial, prism glasses were compared with plain glasses and there was no difference in personnel use. However, for purposes of costing, the resource use in the intervention arm was used and assumed to be on top of usual care. The resource use and costs are summarised in **Table 42** below.

Table 42: Intervention costs – prism intervention for spatial awareness and/or visual neglect

Resources	Frequency	Unit costs	Cost per patient
10 sessions with an occupational therapist[(a)]	30 minutes per session	£45 per hour[(c)]	£225
Prisms glasses[(b)]	n/a	£44.95 excluding VAT	£44.95
Total			£270

(a) Assessment resources could also be required, such as neuropsychological and functional tests.
(b) Prism glasses cost: Manufacturer website [234]. Assumed that each patient would use one pair of glasses. If glasses are reused, costs would be lower.
(c) Estimated based on data and methods from Personal Social Services Research Unit 'Units costs of health and social care' report and Agenda for change hospital salary band 6[51] (typical salary band identified by clinical GDG members).

8.1.1.3 Evidence statements

Clinical evidence statements

One study [215] of 36 participants found that there was no significant difference in total BIT score between those who received computerised scanning and attention training and those who received usual care at the end of intervention period (post-treatment) (LOW CONFIDENCE IN EFFECT).

Two studies [191,215] of 52 participants found that there was no significant difference in total BIT score between those who received computerised scanning and attention training or repetitive prism and those who received usual care at 6 months follow-up (LOW CONFIDENCE IN EFFECT).

Two studies [80,264] of 54 participants found that there was no significant difference in BIT conventional score between those who received feedback glasses and those who received usual care at the end of intervention period (post-treatment) (VERY LOW CONFIDENCE IN EFFECT).

Three studies [80,191,264] of 70 participants found that there was no significant difference in BIT conventional score between those who received feedback glasses or repetitive prisms and those who received usual care at up to 1 month follow-up (LOW CONFIDENCE IN EFFECT).

Two studies [80,216] of 58 participants found that there was no significant difference in BIT behavioural score between those who received feedback glasses or limb activation treatment with perceptual training and those who received usual care, either at the end of intervention period (post-treatment)(MODERATE CONFIDENCE IN EFFECT) or at 2-3 months follow-up (MODERATE CONFIDENCE IN EFFECT).

One study [216] of 40 participants found that there was no significant difference in BIT behavioural score between those who received limb activation treatment with perceptual training and those who received usual care at the end of 6 months follow-up (VERY LOW CONFIDENCE IN EFFECT).

Two studies [191,263] of 50 participants found that there was no significant difference in line bisection score and star cancellation between those who received repetitive prisms or right half-field eye patching and those who received usual care at the end of intervention period (post-treatment) (LOW CONFIDENCE IN EFFECT).

Two studies [191,222] of 55 participants found that wearing repetitive prism was associated with a statistically significant greater improvement in line bisection, compared to those receiving usual care at the end of follow-up (LOW CONFIDENCE IN EFFECT).

One study [191] of 16 participants found no significant difference in star cancellation between those who were wearing repetitive prisms and those receiving usual care at the end of 1 month follow-up (VERY LOW CONFIDENCE IN EFFECT).

One study [130] of 50 participants found no significant difference in overall Rivermead Perceptual Assessment Battery (RPAB) score between spatiomotor cueing and usual care at the end of the trial (LOW CONFIDENCE IN EFFECT).

One study [130] of 50 participants found no significant difference in spatiomotor cueing and perceptual training the cancellation subtest from Rivermead Perceptual assessment Battery (RPAB), compared to usual care at the end of intervention period (post-treatment) (LOW CONFIDENCE IN EFFECT).

One study [130] of 50 participants found that spatiomotor cueing and perceptual training was associated with a statistically significant greater improvement in the body image subtest from Rivermead Perceptual Assessment Battery (RPAB), compared to usual care at the end of the intervention period (post-treatment) (MODERATE CONFIDENCE IN EFFECT).

Two studies [215,263] of 70 participants found that computer based attention training or right half-field eye patching was associated with a statistically significant greater improvement in letter cancellation, compared to usual care at the end of intervention period (post-treatment) (LOW CONFIDENCE IN EFFECT).

One study [215] of 36 participants found that there was no significant difference in letter cancellation between participants receiving computer-based attention training and those receiving usual care at the end of 6 months follow-up (LOW CONFIDENCE IN EFFECT).

One study [222] of 39 participants found that prism training was associated with a statistically significant greater improvement compared to usual care at the end of intervention period (post-treatment) on the following outcomes:

- Tangent screen examination (LOW CONFIDENCE IN EFFECT)
- Line cancellation (LOW CONFIDENCE IN EFFECT).

Two studies [191,263] of 50 participants found that there was no significant difference in representational drawing test between participants who received repetitive prisms training or right half-field eye patching and those who received usual care at the end of intervention period (post-treatment) (VERY LOW CONFIDENCE IN EFFECT).

One study [191] of 16 participants found that there was no significant difference in representational drawing test between those who received repetitive prism and usual care at the end of 1 month follow-up (VERY LOW CONFIDENCE IN EFFECT).

One randomised control study[166] comprising 29 participants, who had tested positive for visual neglect, reported improvements for both the experimental (prismatic lenses of 5 degrees plus pointing task) and control group (sham lenses plus pointing task). However, participants wearing prismatic lenses did not improve significantly more than the control participants (VERY LOW CONFIDENCE IN EFFECT).

Economic evidence statements

No cost effectiveness evidence was identified.

8.1.2 Recommendations and link to evidence

Recommendations	**40. Screen people after stroke for cognitive deficits. Where a cognitive deficit is identified, carry out a detailed assessment using valid, reliable and responsive tools before designing a treatment programme.** **41. Provide education and support for people with stroke and their families and carers to help them understand the extent and impact of cognitive deficits after stroke, recognising that these may vary over time and in different settings.** **42. Assess the effect of visual neglect after stroke on functional tasks such as mobility, dressing, eating and using a wheelchair, using standardised assessments and behavioural observation.** **43. Use interventions for visual neglect after stroke that focus on the relevant functional tasks, taking into account the underlying impairment. For example:** • **interventions to help people scan to the neglected side, such as brightly coloured lines or highlighter on the edge of the page** • **alerting techniques such as auditory cues** • **repetitive task performance such as dressing** • **altering the perceptual input using prism glasses.**
Relative value placed on the outcomes considered	The GDG considered that interventions which were designed to address the underlying impairment might be evaluated using measures of the extent of the impairment such as line bisection or cancellation tests. However, the GDG also felt that it was important to assess the impact of interventions on functional activity, and that studies should report on functional performance as well as impairment level measures.
Quality of evidence	All the included studies for this question looked at improving visual neglect. The GDG noted that all the studies were small and had limitations in terms of study design. Confidence in the effects shown ranged from moderate to very low for all outcomes. The included studies used different interventions including feedback /prismatic glasses, computerised scanning and attention training, or perceptual training plus limb activating device perception training, attentional motor integration and prisms.

	Some benefit was found for prisms and computerised scanning [191,215,222,263] as measured by letter or line cancellation and line bisection test outcomes. The GDG noted that unique intervention delivered in the study by Fanthome [80] and that this has not been reproduced by any other research study.
Trade-off between clinical benefits and harms	The GDG agreed that prisms offered small benefits at the impairment level with no evidence of functional benefit. Although little evidence of clinically important benefit was found, there was no evidence of harms associated with the interventions either. The GDG agreed that given the limited evidence available and the limitations of the studies a recommendation for assessment would be more appropriate. Although no particular intervention could be recommended the GDG were of a view that it was important to offer therapies that addressed the individual's cognitive impairment in order to maximise an individual's ability to engage in everyday activities, and that this was best done by addressing both impairments and activity limitations, for example by encouraging scanning during the performance of a dressing task.
Economic considerations	No cost effectiveness studies were found for this question. The typical cost per patient for delivering an intervention that addresses neglect was estimated based on the study by Turton and colleagues [264] at £270. The GDG considered that the cost of providing this or other interventions was likely to be offset by the potential benefits to patients in terms of their ability to engage in everyday activities, and thus improved quality of life.
Other considerations	The GDG acknowledged that people often have multiple interacting cognitive difficulties. The research tends to focus on these difficulties in isolation but in real life treatment modalities should recognise the complexity of the individual's difficulties. The GDG considered the research presented on the individual cognitive deficits but have also made recommendations based on the real life problems patients experience. Identification of cognitive deficits is often done by formal neuro psychometric screening in these studies. The GDG agreed the assessment of outcome is extremely complex, and the use of individual psychometric tests as an outcome should be used and interpreted with caution, because they are assessments, while the outcomes used to measure cognitive performance are also typically multifaceted addressing attention, memory and perceptual issues. An alternative way of considering outcome is to consider goal achievement, but the GDG agreed there are differing views on whether this is an appropriate outcome to use. It was acknowledged that standard assessments are used along with behavioural observation to assess the effect of visual neglect on usual functional activities. The GDG acknowledged the stoke quality standard to screen for cognitive impairment [189] and agreed that it was important to make a general recommendation about it. The GDG also highlighted the need for health professionals to provide information and support to patients and their carers on the impact that cognitive impairment may have. The GDG agreed that this was a potential topic for further research.

8.2 Memory function

Memory is the ability to encode, store and retrieve information. Memory problems are a common cognitive complaint following stroke. Memory rehabilitation programmes either attempt to retrain impaired memory functions, or teach patients strategies to cope with them. Factors that can contribute to memory difficulties include attention and executive function. In addition, the presence of low mood and/or apathy also needs to be assessed as both of these are associated with stroke and can present with memory problems.

A comprehensive assessment of memory will examine recognition and recall memory in verbal and nonverbal domains as well as new learning of information. Remembering to do something in the future (prospective memory) needs to be distinguished from remembering information from the past (retrospective memory).

Different types of memory impairment impact on function in various ways. For example, the impact of memory impairments may be seen as difficulties in remembering recent information such as a therapist's name, the cause of stroke, or when a relative last visited.

Difficulty with prospective memory may result in forgetting to perform tasks such as taking tablets, or practicing an exercise programme. Both of these memory deficits impact on rehabilitation. Other forms of deficits may impact more significantly on families and carers. Autobiographical and semantic knowledge accumulated during life through reading or verbal communication and experiences is usually relatively well preserved although detailed examination may reveal patchy loss. Impaired nonverbal memory may result in people with stroke becoming lost in particular situations such as when they are out in the community.

8.2.1 Evidence review: In people after stroke what is the clinical and cost-effectiveness of memory strategies versus usual care to improve memory

Clinical Methodological Introduction	
Population:	Adults and young people 16 or older who have had a stroke.
Intervention:	• Mnemonic strategies 'association' and 'organisation', • drill-and-practice, • memory aids internal, • external or both, • errorless learning. Interventions have been separated into three groups: Compensatory strategies, Restorative strategies and Rehearsal – drill and practice strategies.
Comparison:	Usual care
Outcomes:	• Wechsler Memory Scale • Rivermead behavioural memory assessment, • Cognitive Failures Questionnaire • Dysexecutive Questionnaire • Everyday Memory Questionnaire

8.2.1.1 Clinical evidence

Searches were conducted for systematic and RCTs comparing the effectiveness of memory strategies with usual care for adults and young people 16 or older who have had a stroke. Only studies with a minimum sample size of 10 participants (5 in each arm) and including at least 50% of participants with stroke were selected. Two randomised controlled trials (RCTs) were identified. **Table 43** below summarises the population, intervention and outcomes for each of the studies.

Table 43: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix F.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Doornhein	First time stroke	Memory training: Twice a	Pseudo training:	• For target

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
1998[70]	patients admitted to a rehabilitation centre with cognitive/memory and sensory-motor deficits	week for 4 weeks. Mnemonic strategies including "association" and "organisation". Homework books were also used. (N=6)	"Drill and practice" exercises including spending more time repeating material (N=6)	memory tasks: Name-Face Paired Associated Memory Test, Stylus Maze test. • For Control memory task: 15 Words Test, Oxford Recurring faces Test, • Subjective Memory Questionnaire.
Aben[2,119]	Patients who have had a stroke if 18 months or more had elapsed since their first and only stroke. Subjective memory complaints were assessed using a semi structured telephone interview. Patients who reported memory problems but nevertheless were able to adequately deal with these deficits by using memory aids were excluded.	Memory self-efficacy training - training in memory strategies in 9 twice weekly sessions. There were 4 parts: (1) information on memory and stroke (2) training in internal and external memory strategies (visualisation, diary use and taking notes) (3) psychoeducation (4) realistic goal setting regarding memory-demanding tasks.	Peer support groups in 9 twice weekly sessions in which general education on causes and consequences of stroke was provided.	• Memory Self-efficacy (MSE) • Delayed recall from the auditory verbal learning task (AVLT) • Delayed recall from the Rivermead Behavioural Memory Test (RBMT) • Quality of life score (EQ5D)

Comparison: Cognitive rehabilitation (memory strategies) for improving memory versus usual care

Quality assessment						Summary of Findings				
						Memory self-efficacy training – mean unadjusted change score (SE)	Control (peer support) – mean unadjusted change score (SE)	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision			Mean Difference (95% CI)	Baseline adjusted beta value*	Confidence (in effect)
Memory self-efficacy score (follow-up 10 days; Better indicated by higher values)										
1 Aben 2012 [2]	randomised trials	serious(a)	no serious inconsistency	no serious indirectness	serious(b)	0.48 (0.14)	0.12 (0.12)	0.40 (0.07 to 0.73)	beta 0.40 higher (0.07 higher to 0.73 higher)	Low
Delayed recall AVLT (follow-up 10 days; Better indicated by higher values)										
1 Aben 2012 [2]	randomised trials	serious(a)	no serious inconsistency	no serious indirectness	serious(b)	1.01 (0.26)	1.22 (0.29)	-0.11 (-0.93 to 0.71)	beta 0.11 lower (0.93 lower to 0.71 higher)	Low
Delayed recall RBMT (follow-up 10 days; Better indicated by higher values)										
1 Aben 2012 [2]	randomised trials	serious(a)	no serious inconsistency	no serious indirectness	serious(b)	-0.01 (0.49)	0.97 (0.46)	-0.63 (-2.02 to 0.76)	beta 0.63 lower (2.02 lower to 0.76 higher)	Low
Quality of Life EQ5D (follow-up 10 days; Better indicated by higher values)										
1 Aben 2012 [2]	randomised trials	serious(a)	no serious inconsistency	no serious indirectness	no serious imprecision	-0.02 (0.02)	0.00 (0.02)	-0.02 (-0.04 to 0.08)	beta 0.02 lower (0.04 lower to 0.08 higher)	Moderate

* Note. A positive (or negative) number means that the intervention group scored (higher (or lower) than the control group at follow-up adjusted for baseline. The beta-value is an indicator of the influence that grouping has on the change from baseline the higher this value the larger the between group difference.
(a) The study was downgraded for unclear randomisation sequence generation.
(b) The confidence interval crosses one default MID (0.5 of Standard mean difference)

Narrative summary

The following study is summarised as a narrative because the results were not presented in numerical data that could be included in the GRADE table:

One unblinded study [70] of 12 patients reported that mnemonic strategy treatment showed a significant improvement in the trained memory skills, but there was no improvement on control memory tasks. Subjective ratings of every day memory functioning did not differ between the two groups.

8.2.1.2 Economic evidence

Literature review

No relevant economic evaluations comparing cognitive rehabilitation memory strategies with usual care to improve memory were identified.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

In practice most cognitive rehabilitation would be based on compensatory strategies or environmental manipulation, and not the interventions within the trials considered. Typical costs of delivering an intervention aimed at improving memory in patients who have had a stroke was therefore estimated based on resource use estimates provided by clinical members of the GDG. These costs are summarised in **Table 28**. In addition, if computer programs are used, additional costs would be incurred.

Table 44: Intervention costs – cognitive rehabilitation for memory

Resources	Frequency	Unit costs[(a)]	Cost per patient
Initial assessment by a psychologist	2 hours	£136 per hour	£272
Goal setting with multi-disciplinary team	1 hour, with 15 minutes allocated to memory goals	£136 per hour – psychologist £35 per hour – nurse £45 per hour – physiotherapist £45 per hour – occupational therapist £132 per hour – medical consultant	£98
Intervention if inpatient: occupational therapist and psychologist sessions	45 minutes per session, twice a week for 6 weeks	£136 per hour – psychologist £45 per hour – occupational therapist	£1629
Intervention if in the community: occupational therapist and psychologist sessions	45 minutes per session, once a week for 6 weeks	£136 per hour – psychologist £45 per hour – occupational therapist	£815
Total personnel cost (incremental over usual care)			In-patient: £1999 Community: £1184

a) Estimated based on data and methods from Personal Social Services Research Unit 'Unit costs of health and social care' report and the following Agenda for Change salary bands- psychologist (band 8), physiotherapist and occupational therapist (band 6), nurse (band 5) [51] (typical salary bands identified by clinical GDG members).

8.2.1.3 Evidence statements

Clinical evidence statements

One study [2] of 153 participants found that there was no significant difference in delayed recall AVLT between the participants who received memory self-efficiency training and those who received usual care (peer support) (LOW CONFIDENCE IN EFFECT).

One study [2] of 153 participants found that there was no significant difference in delayed recall RBMT between the participants who received memory self-efficiency training and those who received usual care (peer support) (LOW CONFIDENCE IN EFFECT).

One study [2] of 153 participants found that there was no significant difference in Quality of Life (EQ5D) between the participants who received memory self-efficiency training and those who received usual care (peer support) (MODERATE CONFIDENCE IN EFFECT).

One study [2] of 153 participants found that a significant improvement in in memory self-efficacy scores between the participants who received memory self-efficacy training and those who received usual care (peer support) (LOW CONFIDENCE IN EFFECT).

Economic evidence statements

No cost effectiveness evidence was identified.

8.2.2 Recommendations and link to evidence

Recommendations:	**44. Assess memory and other relevant domains of cognitive functioning (such as executive functions) in people after stroke, particularly where impairments in memory affect everyday activity.** **45. Use interventions for memory and cognitive functions after stroke that focus on the relevant functional tasks, taking into account the underlying impairment. Interventions could include:** • **increasing awareness of the memory deficit** • **enhancing learning using errorless learning and elaborative techniques (making associations, use of mnemonics, internal strategies related to encoding information such as 'preview, question, read, state, test')** • **external aids (for example, diaries, lists, calendars and alarms)** • **environmental strategies (routines and environmental prompts).**
Relative value placed on the outcomes considered	The GDG considered that recalling information in the memory of stroke patients after a delay was the most important outcome for this recommendation. They also thought that being able to reflect back on things that happened previously would benefit general wellbeing and therefore positively affect quality of life which was another reported outcome.
Trade-off between clinical benefits and harms	The GDG agreed that rehabilitation is about acquiring skills regardless of the time period between the onset of stroke and introduction of an intervention. Memory problems may have long term impact on a variety of tasks, so assessments should reflect this and interventions need to be tailored and delivered accordingly.

	The GDG noted that memory self-efficiency training (including training on strategies to aid retention of information) did not provide conclusive evidence for a general memory improvement, which conflicted with experience from clinical practice,
Economic considerations	No cost effectiveness studies were found. Personnel cost for delivering a memory intervention programme was estimated at £1999 (inpatient)/£1184 (community) based on GDG estimates of the resource use involved. The GDG considered that very few rehabilitation units would have computer software available currently; therefore these would incur additional costs. The GDG considered that the additional costs would potentially be offset by the long term benefit to patients in terms of improved quality of life.
Quality of evidence	The GDG noted that one of the two studies [70] considered was very small and had limitations in terms of study design and imprecision around the estimate of effect. The other study[2] was methodologically better conducted and included over a hundred participants who have had a stroke. However, it used a particular framework with the aim to increase memory efficiency rather than memory capacity or ability to use memory in everyday situations. The Doornhein [70] study found that teaching mnemonic strategies of 'association' and 'organisation' was linked to improved performance in specific trained memory tasks, but did not transfer to other tasks. The Aben study(2012)[2] did find an improvement in memory efficiency, but no general improvement in delayed recall. Since the intervention was memory self-efficiency training the GDG felt that an improvement in this ability on its own was not a very convincing result. The GDG considered that the type of memory domains addressed in the studies did not address the range of memory difficulties that may be faced by patients. Rote learning and delayed recall is not necessarily directly translatable into improvements in daily functional abilities.
Other considerations	The GDG considered well-established research on similar memory problems in other neurological conditions, and in these studies it was found that patients do benefit from the use of some compensatory strategies, such as the use of mnemonics, diaries, lists, alarms and employing environmental prompts or following a certain routine to help with memory deficit. Similar strategies should be taught to people who have had a stroke where appropriate. It is important in this respect that the strategies are adapted to the individual's learning style and particular impairment rather than having one general training schedule to fit all. The GDG agreed that further research is required. The group agreed that memory needs to be assessed and where memory impacts on everyday activity interventions should be targeted at that activity, taking into account the underlying memory problems. The GDG noted that the success of other rehabilitative interventions may be contingent on memory and therefore the impact of memory on function is important and should not be underestimated.

8.3 Attention function

Attention problems can occur following stroke and are common in people with damage to the right side of their brain. It is best described as the sustained focus on salient information while filtering or ignoring extraneous information. Attention is a very basic function that often is a precursor to all other neurological/cognitive functions. Five different types of attention have been described

- Focused attention: The ability to respond discretely to specific visual, auditory or tactile stimuli.
- Sustained attention: The ability to maintain a consistent behavioural response during continuous and repetitive activity.
- Selective attention: The ability to maintain a behavioural or cognitive set in the face of distracting or competing stimuli.

- Alternating attention: The ability of mental flexibility that allows individuals to shift their focus of attention and move between tasks having different cognitive requirements.
- Divided attention: This is the highest level of attention and it refers to the ability to respond simultaneously to multiple tasks or multiple task demands.

Although there is some spontaneous recovery of attention in some patients, some symptoms may persist for years. Cognitive rehabilitation training aims at managing different aspects of attention and can improve people's ability to participate in daily activity.

Working memory and attention are closely related. Working memory is essential in determining where attention should be directed, filtering information and the ability to inhibit competing stimuli; this can be described as control of attention.

people after stroke what is the clinical and cost effectiveness of sustained attention training versus usual care to improve attention?

Clinical Methodological Introduction	
Population	Adults and young people 16 or older who have had a stroke.
Intervention	Computerised training programme using reaction times and pattern recognition.
Comparison	Usual care
Outcomes	• Test of everyday attention, • • • Cognitive failures Questionnaire • Dis-executive Questionnaire • Everyday Memory Questionnaire

8.3.1.1 Clinical evidence

Searches were conducted for systematic reviews or RCTs that compared sustained attention training versus usual care to improve attention in adults or young people 16 or older who have had a stroke. Only studies with a minimum sample size of 10 participants (5 in each arm) and including at least 50% of participants with stroke were selected. Two RCTs were identified. **Table 45** below summarises the population, intervention and outcomes for the included studies.

Table 45: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix F.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Barker Collo 2009[16]	Acute stroke survivors admitted to New Zealand hospitals who experienced an attention deficit within 2 weeks post stroke	Attention process training (APT): sustained, selective, alternating, and divided attention training (for example number cancellation with visual distractor, sustained attention in noise using audio CDs, flexible shape cancellation, set-dependent alternating attention tasks) administered by a registered clinical neuropsychologist.	Standard care (not specified in the paper). (N=40)	Integrated Visual Auditory Continuous Performance test (IVA-CPT) • Full attention, • Auditory attention, • Visual attention.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
		Participants received up to 30 hours of individual APT for 1 hour on weekdays for 4 weeks (mean 13.5hours). (N=38)		
Westerberg 2007[284]	Participants aged 34-65 of vocational activity who had experienced stroke 12-36 months ago and had self-reported deficits in attention.	Computerised working memory training: was implemented with a computer software product used at home for about 40 minutes /day, 5 days/ week for 5 weeks. Tasks involved reproducing a light sequence in a visuo-spatial grid, indicating numbers in reverse order, identifying letter positions in a sequence, identifying a letter sequence in pseudo words, finding mismatched letters, etc. Participants reported their daily results via internet to a server at the hospital. Feedback from a psychologist provided via telephone once a week. (N=9)	Usual care: no memory training and no contact with a psychologist. (N=9)	• Wechsler Adult Intelligence Scale: • Span board (measures visuo-spatial WM), • Digit span (measures auditory WM) • Stroop time (sec) • Stroop raw score • Cognitive failure questionnaire scores

Comparison: Cognitive rehabilitation (Sustained attention training) versus usual care

Table 46: Sustained attention training versus usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
						Sustained attention training Mean (SD)	Usual care Mean (SD)	Effect		
No. of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision			Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
IVA-CPT (full attention) changes (5 weeks follow-up) (Better indicated by higher values)										
1 Barker 2009[16]	RCT-single blinded	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	(a)	(a)	2.76 (1.31, 4.21)	MD 2.76 higher (1.31 to 4.21 higher)	High
IVA-CPT (full attention) changes (6 months follow-up) (Better indicated by higher values)										
1 Barker 2009[16]	RCT-single blinded	No serious limitations	No serious inconsistency	No serious indirectness	No serious imprecision	(a)	(a)	2.49 (1.24, 3.74)	MD 2.49 higher (1.24 to 3.74 higher)	High
IVA-CPT (auditory attention) changes (5 weeks follow-up) (Better indicated by higher values)										
1 Barker 2009[16]	RCT-single blinded	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	(a)	(a)	1.96 (0.49, 3.43)	MD 1.96 higher (0.49 to 3.43 higher)	High
IVA-CPT (auditory attention) changes (6 months follow-up) (Better indicated by higher values)										
1 Barker 2009[16]	RCT-single blinded	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision (b)	(a)	(a)	0.83 (-0.46, 2.12)	MD 0.83 higher (0.46 lower to	Moderate

Quality assessment						Summary of findings				
						Sustained attention training Mean (SD)	Usual care Mean (SD)	Effect		
No. of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision			Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
									2.12 higher)	
IVA-CPT (visual attention) changes (5 weeks follow-up) (Better indicated by higher values)										
1 Barker 2009[16]	RCT-single blinded	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	(a)	(a)	1.56 (0.03, 3.09)	MD 1.56 higher (0.03 to 3.09 higher)	High
IVA-CPT (visual attention) changes (6 months follow-up) (Better indicated by higher values)										
1 Barker 2009[16]	RCT-single blinded	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	(a)	(a)	1.41 (0.04, 2.78)	MD 1.41 higher (0.04 to 2.78 higher)	High

[(a)] Mean (SD) changes are not given in the study by group only mean differences were reported.
[(b)] Confidence interval crossed one end of default MID.

Table 47: Computerized working memory training versus usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
						Computerised working memory training Mean (SD)	Usual care Mean (SD)	Effect		Confidence(in effect)
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision			Mean difference (95% CI)	Mean difference (MD) (95% CI)	
Wechsler Adult intelligence Scale-Revised Span board (post-treatment effect) (Better indicated by higher values)										
1 Westerberg 2007[284]	RCT – unclear blinding	Very serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision (b)	6.2 (1.0)	5.7 (1.8)	0.50 (-0.85 to 1.85)	MD 0.50 higher (0.85lower to 1.85 higher)	Very low
Wechsler Adult Intelligence Scale-Revised Digit Span (post-treatment effect) (Better indicated by higher values)										
1 Westerberg 2007[284]	RCT – unclear blinding	Very serious limitations (a)	No serious inconsistency	No serious indirectness	No serious imprecision	7.3 (1.0)	5.7 (1.3)	1.60 (0.53 to 2.67)	MD 1.60 higher (0.53 to 2.67 higher)	Low
Stroop time (sec) (post-treatment effect) (Better indicated by lower values)										
1 Westerberg 2007[284]	RCT – unclear blinding	Very serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision (b)	93 (19)	124 (48)	-31 (-64.73 to 2.73)	MD 31 lower (64.73 lower to 2.73 higher)	Very low
Stroop raw score (post-treatment effect) (Better indicated by higher values)										
1	RCT –	Very serious	No serious	No serious	Serious	91.1 (1.27)	97.8	1.30 (-0.47	MD 1.30	Very low

Quality assessment						Summary of findings				
						Computerised working memory training	Usual care	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Mean (SD)	Mean (SD)	Mean difference (95% CI)	Mean difference (MD) (95% CI)	Confidence(in effect)
Wechsler Adult intelligence Scale-Revised Span board (post-treatment effect) (Better indicated by higher values)										
Westerberg 2007[284]	unclear blinding	limitations (a)	inconsistency	indirectness	imprecision (b)		(2.4)	to 3.07)	lower (0.47 lower to 3.07 higher)	
Cognitive Failure Questionnaire (CFQ scale ranging from 0-100, post-treatment effect) (better indicated by lower values)										
1 Westerberg 2007[284]	RCT – unclear blinding	Very serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision (b)	29.2 (12.1)	43 (13.8)	-13.8 (-25.79 to -1.81)	MD 13.8 lower (25.79 lower to 1.81 lower)	Very low

(a) No details on randomisation. Unclear allocation concealment and blinding.
(b) Confidence interval crossed one end of default MID (0.5 of the standard mean difference).

8.3.1.2 Economic evidence

Literature review

No relevant economic evaluations comparing cognitive rehabilitation sustained attention training with usual care to improve attention were identified.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

The GDG advised to estimate intervention costs based on the resources described in Barker, 2009[16] The estimated cost of the software to perform an unlimited number of Integrated Visual Auditory Continuous Performance Tests (IVA-CPT) was £1244[k] excluding VAT (obtained from www.bio-medical.com[26]). Personnel costs, incremental over usual care, are outlined in **Table 48**.

Table 48: Intervention costs – personnel costs associated with IVA-CPT

Resources	Frequency	Unit costs	Cost per patient
Baseline neuropsychological assessment [(a)]	2.5 hours repeated at 5 weeks and 6 months	£136 per hour[(b)]	£1,020
Individual Attention Process Training (APT) sessions[(a)]	30 hours	£136 per hour[(b)]	£4,080
Total personnel cost (incremental over usual care)			£5,100

(a) Delivered by a neuropsychologist

(b) Clinical psychologist costs used as costs for a neuropsychologist could not be obtained. Estimated based on data and methods from Personal Social Services Research Unit 'Unit costs of health and social care' report and Agenda for Change salary band 8[51] (typical salary band identified by clinical GDG members).

8.3.1.3 Evidence statements

Clinical evidence statements

One study[16] of 78 participants found those who received the sustained attention training experienced a statistically significant improvement in full attention measured by the Integrated Visual Auditory Continuous Performance test (IVA-CPT) at 5 weeks and 6 months follow-up compared to those who received usual care (HIGH CONFIDENCE IN EFFECT).

One study[16] of 78 participants found those who received the sustained attention training experienced a statistically significant improvement in auditory attention measured by the Integrated Visual Auditory Continuous Performance test (IVA-CPT) at 5 weeks follow-up compared to those who received usual care (HIGH CONFIDENCE IN EFFECT).

k US$1895(2011) converted to UK pounds (2010) using purchasing power parities[194]

One study[16] of 78 participants found there was no significant difference on the auditory attention measured by the Integrated Visual Auditory Continuous Performance test (IVA-CPT) at 6 months between participants who received the sustained attention training and those who received usual care (MODERATE CONFIDENCE IN EFFECT).

One study[16] of 78 participants found those who received the sustained attention training experienced a statistically significant improvement in visual attention measured by the Integrated Visual Auditory Continuous Performance test (IVA-CPT) at 5 weeks and 6 months follow-up compared to those who received usual care (HIGH CONFIDENCE IN EFFECT).

One study[284] of 18 participants found that there was no significant difference in Wechsler Adult intelligence Scale-Revised WAIS-R Span Board test between the participants who received computerised memory training and those who received usual care (VERY LOW CONFIDENCE IN EFFECT).

One study[284] of 18 participants found that those who received computerised memory training had a statistically significant improvement in Wechsler Adult intelligence Scale-Revised WAIS-R digit span test, compared with the participants who received usual care. (LOW CONFIDENCE IN EFFECT)

One study[284] of 18 participants found that there was no significant difference the time taken to complete the STROOP task (sec) between the participants who received computerised memory training and those who received usual care (VERY LOW CONFIDENCE IN EFFECT).

One study[284] of 18 participants found that there was no significant difference number of STROOP items correctly named between the participants who received computerised memory training and those who received usual care (VERY LOW CONFIDENCE IN EFFECT).

One study[284] of 18 participants found that those who received computerised memory training had a statistically significant improvement in the score of a Cognitive Failure Questionnaire (CFQ), compared with the participants who received usual care. (VERY LOW CONFIDENCE IN EFFECT)

Economic evidence statements

No cost effectiveness evidence was identified.

8.3.2 Recommendations and link to evidence

Recommendations	**46. Assess attention and cognitive functions in people after stroke using standardised assessments. Use behavioural observation to evaluate the impact of the impairment on functional tasks.** **47. Consider attention training for people with attention deficits after stroke.** **48. Use interventions for attention and cognitive functions after stroke that focus on the relevant functional tasks. For example, use generic techniques such as managing the environment and providing prompts relevant to the functional task.**
Relative value placed on the outcomes considered	The outcomes included in the review were the Integrated Visual Auditory Continuous Performance test (IVA-CPT): full attention, auditory attention, visual attention and Wechsler Adult Intelligence Scale of digit span as well as performance on the STROOP task and scores on the cognitive failure questionnaire.

	The tests used were neuropsychological measures of attention and even though the cognitive failures questionnaire is aimed at testing more functional abilities (such as everyday situations attending to names, and focusing on tasks) the validity of this measure was questioned. The STROOP task was seen as a good measure of attentional capabilities since it requires participants to focus on particular features whilst disregarding other aspects. This is an ability that can be directly translated to more functional performance such as focusing on a task in light of other distractions
Trade-off between clinical benefits and harms	Attention impairment was defined in the study by Barker [16] as performance less than 1 standard deviation below the normative mean on any test. In the second included study[284] attention/memory problems were based on self-report only and the study methodology was poorly described. It was agreed by the GDG that assessments of cognitive impairments may not be clinically relevant, and attention based interventions should be provided when the person with stroke or their carers identify difficulties attributable to attention difficulties. The group agreed that a recommendation for specific interventions could not be made based on these two studies, but recognised that in clinical practice time would be spent with patients to improve attention deficits. Further research is required.
Economic considerations	No cost effectiveness studies were found. The cost of the IVA-CPT software to deliver the intervention used in the study identified for the clinical review was estimated at £1244. In addition, personnel costs were estimated at £5,100 per person based on resources used in the Barker, 2009[16] study. Given the high cost of this specific intervention and the limited evidence of its clinical effectiveness, the evidence was considered insufficient to conclude that it would be cost-effective.
Quality of evidence	One well conducted randomised controlled trial [16] found that attention process training was associated with greater improvement in attention as measured on the IVA-CPT visual scale and Full Scale Attention Quotient at 5 weeks and 6 months follow-up. The Westerberg [284] study found that a computerised working memory training programme improved working memory when measured with the Wechsler Adult Intelligence Scale – Revised Digit Span (an auditory test of working memory), but had no effect when measured by the Wechsler Adult Intelligence Scale – Revised Span board (a visuo-spatial test of working memory). Both of these tests require attentional cognitive resources. It was noted that the time scale addressed in the Westerberg study is 20 months after the onset of stroke and the impact of the intervention may differ if undertaken in the sub-acute stage. No improvement was seen on STROOP performance. However, the intervention resulted in fewer cognitive failures as measured by self-report. The quality of the evidence for these outcomes was low to very low and therefore we do not have confidence in the effects reported by this study. The GDG agreed that usual care would normally consist of a baseline assessment (similar to the one reported by Barker, 2009) but of shorter week day neuropsychological sessions than those reported in the study which were described as one hour per weekday for four weeks. The GDG noted that all interventions have a baseline assessment but the content of the assessment varies. The GDG felt that currently computer based rehabilitation may not be available everywhere, however with increasing familiarity and access of the population to personal computers this would change. The limited evidence found indicates the need for further research to be undertaken.
Other considerations	Even though evidence from one study can be rated as high, the GDG considered that this would need to be replicated to demonstrate a robust effect. However, problems with attention have serious effects on self-esteem and quality of life in general and are quite upsetting for persons who have had a stroke and their carers / family. In particular it affects functional performance in everyday situations, such

	as the focus on tasks that are important whilst ignoring distraction from other environmental factors. It was therefore seen as important to assess possible impairments and adopt an individualised approach to help the person to participate more confidently in activities of daily living.

9 Emotional functioning

9.1 Psychological therapies

Psychological therapies may be characterised as an approach which involves a confiding relationship, that takes place within a therapeutic setting, with a theoretical basis (an understanding of models of normal and abnormal behaviour) involving a therapeutic process which again has an underpinning theoretical model. Therapy can be delivered to an individual, a couple, a family or a group.

Many people who have had a stroke experience distress which can impact negatively on functional outcome. In addition, not only are the physical consequences of stroke associated with emotional disorders, the cognitive aspects of stroke may also impact on their ability to deal with the emotional consequences of the stroke.

Psychological therapies may be useful for individuals with stroke. These interventions emphasise the individual's own residual strengths, clarify the patient's concerns and teach new strategies for coping effectively and managing distress. It is often useful to draw upon a variety of psychological models (for example Behaviour therapy, cognitive behaviour therapy and also theories of change) depending on the individual's presentation.

Psychological therapies may help the individual and their carers with post-stroke emotional disorders and relationship issues. Psychological interventions of this type may also be needed to facilitate an individual and carers understanding and adjustment to cognitive impairments, communication impairments or to physical disabilities. It is critical to note that the impact of physical, cognitive and emotional difficulties are likely to overlap; therefore the delivery of any standard intervention (for example, cognitive behaviour therapy) is likely to need adaptation to suit an individual's cognitive and/or physical presentation. Within the NHS, psychological therapies are provided by members of different professional disciplines, including clinical neuropsychologists, clinical psychologists, specially trained mental health nurses, occupational therapists and counsellors. In the context of stroke, where patients have impairments which impact on their ability to participate in psychological treatments, it is important that the therapist understands the nature and impact of the impairments and how they interact.

9.1.1 Evidence review: In people after stroke what is the clinical and cost-effectiveness of psychological therapies provided to the family (including the patient)?

Clinical Methodological Introduction	
Population:	Family carers (family member or relative, or other unpaid carer support) of people with stroke to include adults and young people over 16 with stroke
Intervention	Family Therapy Cognitive-Behaviour Therapy Relationship counselling (to include Couples therapy) (all interventions may include some form of information)
Comparison:	Usual care (usually nothing)
Outcomes:	• Quality of Life (for both carer and patient) – Any QOL and depression outcomes including the following: stroke impact scale, EuroQoL, care giver burden scale, caregiver strain index, carer strain index, burden of stroke scale, Stroke and aphasia quality of life scale, ASCOT scale. • Occurrence of depression/anxiety/mood in carers –

Clinical Methodological Introduction	
	Beck Depression Inventory, Beck Depression Inventory 2, Geriatric Depression Scale, neuropsychiatry inventory, Hospital Anxiety and Depression Scale (HADS),General health questionnaire, Visual Analogue Mood Scale, SAD-Q.

9.1.1.1 Clinical evidence

Searches were conducted for systematic reviews and RCTs or systematic reviews of observational studies comparing psychological therapies with usual care to improve quality of life for both carer and stroke patients older than 16 years old. One RCT was identified that met the pre-specified protocol. **Table 40** summarises the study characteristics of the included study.

Table 49: Summary of the study included in the clinical evidence review. For full details of the extraction please see Appendix H.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Smith 2012 [242]	Participants were married couples: female care giver (CGs) and her husband who has had a stroke (PWS). Either the caregiver or her husband had to score five or more on the Personal Health Questionnaire (PHQ-9: at least mild depression). Participants were excluded if they were medically unstable or terminally ill and if they were cognitively unable to participate.	The intervention was based on the Stress Process Model. It consisted of an online support program of five components designed to provide the caregivers with knowledge resources and skills to help both themselves and their partner to reduce their personal distress and to provide optimal emotional care to the PWS. Attempts were repeatedly made to acknowledge the positive and negative feelings of both members of the CG-PWS dyad, as well as to illustrate how they were intertwined. CGs were encouraged to interact with PWS in ways to enhance their mutual well-being.	CG – PWS dyads had access to the online resource centre, but had no exposure to the key intervention components.	• Centre for Epidemiological Studies Depression scale (CESD) • Mastery Scale (a measure to assess coping ability) • Self-Esteem scale, • Medical Outcomes Study (MOS) Social Support survey (measuring amount of emotional, informational and affectionate support).

Comparison psychological therapies vs. control to improve mood in caregivers and persons with stroke

Table 50: Web based psychological therapy vs. control outcomes for CAREGIVERS (WIVES) only (baseline adjusted means (sd))

Quality assessment						Summary of Findings				
								Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Web based psychological intervention Frequency (%)/ mean (SD)/ median (range)	Control Frequency (%)/ mean (SD)/ median (range)	Relative Risk / Mean difference/ (95% CI)	Absolute effect or mean difference (MD) (95% CI)	Confidence (in effect)
Centre for Epidemiological Studies Depression scale (CESD) - Post-test (follow-up 11 weeks; range of scores: 0-60; Better indicated by lower values)										
1 Smith 2012[242]	randomised trials	serious (a)	no serious inconsistency	no serious indirectness	serious(b)	13.9 (7.7)	19.7 (7.4)	-5.8 (-11.07 to -0.53)	MD 5.8 lower (11.07 to 0.53 lower)	LOW
Centre for Epidemiological Studies Depression scale (CESD) - 1 month follow-up (range of scores: 0-60; Better indicated by lower values)										
1 Smith 2012[242]	randomised trials	serious (a)	no serious inconsistency	no serious indirectness	serious(b)	13.4 (6.2)	16.6 (6.2)	-3.2 (-7.5 to 1.1)	MD 3.2 lower (7.5 lower to 1.1 higher)	LOW
Mastery Scale - Post-test (follow-up 11 weeks; range of scores: 9-36; Better indicated by higher values)										
1 Smith 2012[242]	randomised trials	serious (a)	no serious inconsistency	no serious indirectness	serious(b)	24.2 (2.7)	23.6 (2.5)	0.6 (-1.21 to 2.41)	MD 0.6 higher (1.21 lower to 2.41 higher)	LOW
Mastery Scale - 1 month follow-up (range of scores: 9-36; Better indicated by higher values)										
1 Smith 2012[242]	randomised trials	serious (a)	no serious inconsistency	no serious indirectness	very serious(b)	24.1 (1.9)	24.4 (2.1)	-0.3 (-1.69 to	MD 0.3 lower (1.69 lower to 1.09 higher)	VERY LOW

Quality assessment						Summary of Findings				
								Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Web based psychological intervention Frequency (%)/ mean (SD)/ median (range)	Control Frequency (%)/ mean (SD)/ median (range)	Relative Risk / Mean difference/ (95% CI)	Absolute effect or mean difference (MD) (95% CI)	Confidence (in effect)
								1.09)		
Self-esteem scale - Post-test (follow-up 11 weeks; range of scores: 10-40; Better indicated by higher values)										
1 Smith 2012[242]	randomised trials	serious (a)	no serious inconsistency	no serious indirectness	very serious(c)	31.6 (2.3)	31.9 (2.5)	-0.3 (-1.96 to 1.36)	MD 0.3 lower (1.96 lower to 1.36 higher)	VERY LOW
Self-esteem scale - 1 month follow-up (range of scores: 10-40; Better indicated by higher values)										
1 Smith 2012[242]	randomised trials	serious (a)	no serious inconsistency	no serious indirectness	serious(b)	31.1 (2.7)	32.6 (2.9)	-1.5 (-3.44 to 0.44)	MD 1.5 lower (3.44 lower to 0.44 higher)	LOW
Medical Outcomes Study (MOS) Social Support survey - Post-test (follow-up 11 weeks; range of scores: 11-55; Better indicated by higher values)										
1 Smith 2012[242]	randomised trials	serious (a)	no serious inconsistency	no serious indirectness	very serious(c)	37 (6.6)	37 (6.6)	0 (-4.58 to 4.58)	MD 0 higher (4.58 lower to 4.58 higher)	VERY LOW
Medical Outcomes Study (MOS) Social Support survey - 1 month follow-up (range of scores: 11-55; Better indicated by higher values)										
1 Smith 2012[242]	randomised trials	serious (a)	no serious inconsistency	no serious indirectness	very serious(c)	33.8 (6.2)	36.3 (6.2)	-2.5 (-6.8 to 1.8)	MD 2.5 lower (6.8 lower to 1.8 higher)	VERY LOW

(a) Allocation concealment is unclear and there are baseline differences (which would underestimate effects of intervention) and no participant blinding.

(b) The confidence interval crosses one default MID

[c]*The confidence interval of the overall effect crosses the default MID favouring the intervention and the default MID favouring the control group*

Table 51: Web based psychological therapy vs. control outcomes for PERSONS WITH STROKE (HUSBANDS) only (baseline adjusted means (sd))

Quality assessment						Summary of Findings				
								Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Web based psychological intervention Frequency (%)/ mean (SD)/ median (range)	control Frequency (%)/ mean (SD)/ median (range)	Relative Risk / Mean difference/ (95% CI)	Absolute effect or mean difference (MD) (95% CI)	Confidence in effect
Centre for Epidemiological Studies Depression scale (CESD) - Post-test (follow-up 11 weeks; range of scores: 0-60; Better indicated by lower values)										
1 Smith 2012[24 2]	randomised trials	serious (a)	no serious inconsistency	no serious indirectness	very serious(b)	19.5 (8.5)	20.4 (8.7)	-0.9 (-6.86 to 5.06)	MD 0.9 lower (6.86 lower to 5.06 higher)	VERY LOW
Centre for Epidemiological Studies Depression scale (CESD) - 1 month follow-up (range of scores: 0-60; Better indicated by lower values)										
1 Smith 2012[24 2]	randomised trials	serious (a)	no serious inconsistency	no serious indirectness	serious(c)	14 (8.1)	17.9 (7.8)	-3.9 (-9.45 to 1.65)	MD 3.9 lower (9.45 lower to 1.65 higher)	LOW
Mastery Scale - Post-test (follow-up 11 weeks; range of scores: 9-36; Better indicated by higher values)										
1 Smith 2012[24 2]	randomised trials	serious (a)	no serious inconsistency	no serious indirectness	serious(c)	21.6 (4.6)	22.8 (4.9)	-1.2 (-4.53 to 2.13)	MD 1.2 lower (4.53 lower to 2.13 higher)	LOW
Mastery Scale - 1 month follow-up (range of scores: 9-36; Better indicated by higher values)										
1 Smith 2012[24 2]	randomised trials	serious (a)	no serious inconsistency	no serious indirectness	very serious(b)	24.6 (4.3)	24.4(4.5)	-0.2 (-2.85 to 3.25)	MD 0.2 higher (2.85 lower to 3.25 higher)	VERY LOW
Self-esteem scale - Post-test (follow-up 11 weeks; range of scores: 10-40; Better indicated by higher values)										
1	randomise	serious	no serious	no serious	serious(c)	26.7(3.9)	27.7(3.7)	-1 (-3.64 to	MD 1 lower	

Quality assessment						Summary of Findings				
								Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Web based psychological intervention Frequency (%)/ mean (SD)/ median (range)	control Frequency (%)/ mean (SD)/ median (range)	Relative Risk / Mean difference/ (95% CI)	Absolute effect or mean difference (MD) (95% CI)	Confidence in effect
Smith 2012[24] 2	d trials	(a)	inconsistency	indirectness				1.64)	(3.64 lower to 1.64 higher)	LOW
Self-esteem scale - 1 month follow-up (range of scores: 10-40; Better indicated by higher values)										
1 Smith 2012[24] 2	randomised trials	serious (a)	no serious inconsistency	no serious indirectness	serious(c)	28.5 (4.6)	27.2 (4.9)	1.3 (-2.03 to 4.63)	MD 1.3 higher (2.03 lower to 4.63 higher)	LOW
Medical Outcomes Study (MOS) Social Support survey - Post-test (follow-up 11 weeks; range of scores: 11-55; Better indicated by higher values)										
1 Smith 2012[24] 2	randomised trials	serious (a)	no serious inconsistency	no serious indirectness	very serious(b)	41.5 (6.6)	41 (6.6)	0.5 (-4.08 to 5.08)	MD 0.5 higher (4.08 lower to 5.08 higher)	VERY LOW
Medical Outcomes Study (MOS) Social Support survey - 1 month follow-up (range of scores: 11-55; Better indicated by higher values)										
1 Smith 2012[24] 2	randomised trials	serious (a)	no serious inconsistency	no serious indirectness	very serious(b)	43.2 (4.6)	44 (4.9)	-0.8 (-4.13 to 2.53)	MD 0.8 lower (4.13 lower to 2.53 higher)	VERY LOW

[(a)]Allocation concealment is unclear and there are baseline differences (which would underestimate effects of intervention) and no participant blinding.

[(b)]The confidence interval of the overall effect crosses the default MID favouring the intervention and the default MID favouring the control group

[(c)]The confidence interval crosses one default MID

9.1.1.2 Economic evidence

Literature review

No relevant economic evaluations comparing psychological therapies for the family with usual care were identified.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

Before delivering the psychological therapy for mood to the patient, some screenings would be requires to assess the patient's neuropsychological profile. A brief screening of cognition and communication could determine if there are any gross issues which might form barriers to effective participation in therapy. If there are none, psychological therapies could be started right away. Where issues are indicated with cognition, communication or behaviour, at a level that may affect delivery of and engagement to therapy, additional neuropsychological assessment would be required to assess the patient's capabilities and capacity for participating in psychological therapy and to provide a basis for any possible adaptations to therapy.

The initial neuropsychological assessment test kit varies and would come in at approximately one off cost of £2000 to £3000 depending on which tests are purchased as this is usually down to the clinicians' discretion and this is usually updated annually for a one off cost of £500. Assessments are carried out by a Band 8 clinician and could take between 2 – 4 hours. The estimated cost per hour of client contact for a community-based clinical psychologist (Band 8a) is £136[l]; therefore the assessment cost would be between £272 and £544 per patient.

The psychological therapy for mood for the patient usually involves an indirect consultation with the multi-disciplinary team and family and direct clinical consultation with the person who has had a stroke. (If a clinical consultation is needed, the package of therapy would be negotiated with the patient)

Both assessment and therapy input vary according to the patient's need. As a ballpark figure up to 12 sessions of psychological therapy may be offered to stroke patients for depression; usually one session is carried out per week and each session would take between 45 minutes and one hour. The estimated cost per hour of client contact for clinical psychologist (band 8a) is £136[m]. The total average cost of therapy would be £1,224 per patient.

In the event that the psychologist identifies more significant mood disorder for which psychological therapy is not appropriate, pharmacological treatment and the neuropsychiatric input would be required for both assessment and prescription of pharmacological therapy.

9.1.1.3 Evidence statements

Research into psychological therapy for this group of patients is well-known to be very difficult and in its relative infancy and therefore the evidence pool is very limited.

l Estimated based on data and methods from Personal Social Services Research Unit 'Unit costs of health and social care' report and Agenda for Change salary band 8a[51] (typical salary band identified by clinical GDG members).

m Estimated based on data and methods from Personal Social Services Research Unit 'Unit costs of health and social care' report and Agenda for Change salary band 8a[51] (typical salary band identified by clinical GDG members).

Clinical evidence statements

For caregivers:

One study[242] comprising 32 pairs of female caregivers and their husbands found that caregivers' depression, as measured by the Centre for Epidemiological Studies Depression scale (CESD), statistically improved when they received an online psychological intervention compared to those in the control condition at the end of the 11 week intervention period (LOW CONFIDENCE IN EFFECT)

One study[242] comprising 32 pairs of female caregivers and their husbands found that there was no significant improvement in caregivers' depression, as measured by the Centre for Epidemiological Studies Depression scale (CESD), when they received an online psychological intervention compared to those in the control condition at 1 month follow-up after the end of intervention (LOW CONFIDENCE IN EFFECT)

One study[242] comprising 32 pairs of female caregivers and their husbands found that there was no significant improvement in caregivers' level of coping, as measured by the Mastery Scale, when they received an online psychological intervention compared to those in the control condition at the end of the 11 week intervention period (LOW CONFIDENCE IN EFFECT)

One study[242] comprising 32 pairs of female caregivers and their husbands found that there was no significant improvement in caregivers' level of coping, as measured by the Mastery Scale, when they received an online psychological intervention compared to those in the control condition at 1 month follow-up after the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

One study[242] comprising 32 pairs of female caregivers and their husbands found that there was no significant improvement in caregivers' level of self- esteem, when they received an online psychological intervention, compared to those in the control condition at the end of the 11 week intervention period (VERY LOW CONFIDENCE IN EFFECT)

One study[242] comprising 32 pairs of female caregivers and their husbands found that there was no significant improvement in caregivers' level of self-esteem, when they received an online psychological intervention compared to those in the control condition at 1 month follow-up after the end of intervention (LOW CONFIDENCE IN EFFECT)

One study[242] comprising 32 pairs of female caregivers and their husbands found that there was no significant improvement in caregivers' level of social support skills, when they received an online psychological intervention, compared to those in the control condition at the end of the 11 week intervention period (VERY LOW CONFIDENCE IN EFFECT)

One study[242] comprising 32 pairs of female caregivers and their husbands found that there was no significant improvement in caregivers' level of social support skills, when they received an online psychological intervention compared to those in the control condition at 1 month follow-up after the end of intervention (LOW CONFIDENCE IN EFFECT)

For the person who has had a stroke:

One study[242] comprising 32 pairs of female caregivers and their husbands found that there was no significant improvement in the level of depression of the person who has had a stroke, as measured by the Centre for Epidemiological Studies Depression scale (CESD) when they received an online psychological intervention compared to those in the control condition at the end of the 11 week intervention period (VERY LOW CONFIDENCE IN EFFECT)

One study[242] comprising 32 pairs of female caregivers and their husbands found that there was no significant improvement in the level of depression of the person who has had a stroke, as measured by the Centre for Epidemiological Studies Depression scale (CESD), when they received an online

psychological intervention compared to those in the control condition at 1 month follow-up after the end of intervention (LOW CONFIDENCE IN EFFECT)

One study[242] comprising 32 pairs of female caregivers and their husbands found that there was no significant improvement in the level of coping of the person who has had a stroke, as measured by the Mastery Scale, when they received an online psychological intervention compared to those in the control condition at the end of the 11 week intervention period (LOW CONFIDENCE IN EFFECT)

One study[242] comprising 32 pairs of female caregivers and their husbands found that there was no significant improvement in the level of coping of the person who has had a stroke, as measured by the Mastery Scale, when they received an online psychological intervention compared to those in the control condition at 1 month follow-up after the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

One study[242] comprising 32 pairs of female caregivers and their husbands found that there was no significant improvement in the level of self- esteem of the person who has had a stroke, when they received an online psychological intervention, compared to those in the control condition at the end of the 11 week intervention period (LOW CONFIDENCE IN EFFECT)

One study[242] comprising 32 pairs of female caregivers and their husbands found that there was no significant improvement in the level of self-esteem of the person who has had a stroke, when they received an online psychological intervention compared to those in the control condition at 1 month follow-up after the end of intervention (LOW CONFIDENCE IN EFFECT)

One study[242] comprising 32 pairs of female caregivers and their husbands found that there was no significant improvement in the level of social support skills of the person who has had a stroke, when they received an online psychological intervention, compared to those in the control condition at the end of the 11 week intervention period (VERY LOW CONFIDENCE IN EFFECT)

One study[242] comprising 32 pairs of female caregivers and their husbands found that there was no significant improvement in the level of social support skills of the person who has had a stroke, when they received an online psychological intervention compared to those in the control condition at 1 month follow-up after the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

Economic evidence statements

No cost effectiveness evidence was identified.

9.1.2 Recommendations and link to evidence

Recommendations	**49. Assess emotional functioning in the context of cognitive difficulties in people after stroke. Any intervention chosen should take into consideration the type or complexity of the person's neuropsychological presentation and relevant personal history.** **50. Support and educate people after stroke and their families and carers, in relation to emotional adjustment to stroke, recognising that psychological needs may change over time and in different settings.** **51. When new or persisting emotional difficulties are identified at the person's 6-month or annual stroke reviews, refer them to appropriate services for detailed assessment and treatment.** **52. Manage depression or anxiety in people after stroke who have no**

	cognitive impairment in line with recommendations in Depression in adults with a chronic physical health problem (NICE clinical guideline 91) and Generalised anxiety disorder (NICE clinical guideline 113).
Relative values of different outcomes	Any quality of life or depression outcome was included in the clinical review. The study reported depression, ability to cope, self-esteem and emotional support.
Trade-off between clinical benefits and harms	Having a stroke can affect relationships between the individual with stroke and a spouse or partner. Transition to new roles and adaptation to disability are challenging, and have been likened 'to navigating uncharted territory'. The National Service Framework for People with Long-Term (Neurological) Conditions highlighted the need for lifelong care and support for people with long term neurological conditions, their families and carers. In view of this the GDG wished to specifically examine the evidence around supporting families and couples. Only one study was found in this area. This particular intervention used an online support programme to provide caregivers with knowledge and skills to reduce their own personal stress and provide emotional support to the person they were caring for. While the GDG agreed it was important to provide strategies to help people cope effectively and manage distress and a number of different psychological approaches could be drawn upon, of which one could be the use of computer based therapies, it was questioned whether this would be the most suitable format for some people, in particular an older generation. The GDG noted that prevalence of depression in stroke survivors has been estimated at 15 - 20%. They noted that depression in stroke survivors impacts on family members. The GDG agreed that an assessment of emotional functioning should be conducted in all patients with stroke. The GDG considered that whilst it was not possible to provide detail on what the assessment should comprise, a general recommendation should be made as the person's mood would have a major impact on the quality of life of both the patient and their carers. The GDG based their recommendation on consensus opinion.
Economic considerations	No cost effectiveness studies were identified for this question. Both assessment and therapy vary according to the patient's need. Assessments are carried out by a Band 8A clinician and could take between 2 – 4 hours. The estimated cost per hour of client contact for a community-based clinical psychologist (band 8a) is £136[n] therefore the assessment cost would be between £272 and £544 per patient. Up to 12 sessions of psychological therapy may be offered to stroke patients for depression; usually one session is carried out per week and each session would take around one hour. The total average cost of therapy would be £1,224 per patient. In the event that the psychologist identifies more significant emotional difficulties for which psychological therapy is not appropriate, pharmacological treatment and the neuropsychiatric input would be required at this stage for both assessment and prescription of pharmacological therapy. The GDG considered these costs to be likely offset by the benefits and the improvements in the patient's quality of life generated by the psychological therapy.
Quality of evidence	The study demonstrated that caregivers' depression statistically improved

n Estimated based on data and methods from Personal Social Services Research Unit 'Unit costs of health and social care' report and Agenda for Change salary band 8a[51] (typical salary band identified by clinical GDG members).

	when they received an online psychological intervention compared to the depression scores of those in the control condition. This was the only outcome that demonstrated a significant result. However confidence in the results for this outcome was low due to the study being downgraded for serious risk of bias and imprecision. It was not clear at what time point after stroke the study was conducted. The intervention was delivered to people at home, and results were reported at the end of intervention (11 weeks) and at one month follow-up. The GDG agreed that it takes time for the person after stroke to be ready for rehabilitation due to the psychological adjustment required, and this would include carers too. Therefore having only one month follow-up may be a limiting factor of this study. The group agreed that provision of psychological interventions was important for families and carers of people after stroke and further research needs to be conducted in this area.
Other considerations	The GDG agreed with the recommendations made in the NICE guidance on the management of depression in adults with a chronic health problem (CG91), Depression: the treatment and management of depression in adults (CG 90), and Generalised anxiety disorder and panic disorder (with or without agoraphobia) in adults (CG113). They believed these to be applicable to people after stroke with the added observation that due to cognitive and language difficulties psychological therapies need to be delivered by an appropriately trained and supervised professional who has an understanding of the nature of the cognitive and physical difficulties and their impact. The GDG agreed that people presenting with emotional difficulties at their 6 month or annual reviews should be referred for detailed assessment.

10 Vision

Vision may be affected after stroke in a number of ways. People with stroke may be aware of difficulties with peripheral vision as a result of a visual field defect, double vision as a result of impaired eyed movements or poor co-ordination of eye movements, and problems arising as a result of difficulties with visual processing. This chapter focuses on the treatment of hemianopia and double vision.

10.1 Eye movement therapy

Hemianopias are estimated to affect between 8 and 25% of people with stroke[17,92]. This vision defect is characterised by low vision or blindness in corresponding halves of the field of vision. People suffering from hemianopia or quadrantanopia may run into objects, trip or fall, knock things over, and lose their place when reading, or be surprised by people or objects that seem to appear suddenly out of nowhere. Some people may not be aware of the deficit, especially those with associated neglect. Eye movement therapy encourages scanning into the affected visual field and is a technique used with patients with a hemianopia post stroke.

10.1.1 Evidence review: In people after stroke what is the clinical and cost-effectiveness of eye movement therapy for visual field loss versus usual care?

Clinical Methodological Introduction	
Population:	Adults and young people 16 or older who have had a stroke
Intervention:	Eye movement therapy including: • Visual search therapy • Visual scanning • Scanning compensatory training
Comparison:	• Usual care (usually nothing) • Sham visual rehabilitation
Outcomes:	• Reading (speed and accuracy) • Eye movement tasks • Scanning • Letter Cancellation Test

10.1.1.1 Clinical evidence

Searches were conducted for systematic reviews and RCTs comparing eye movement therapy as an intervention for visual field loss in people after stroke. Only studies with a minimum sample size of 10 participants (5 in each arm) and including at least 50% of participants with stroke were selected. Three RCTs were identified. **Table 52** summarises the population, intervention, comparison and outcomes for each of the studies.

Table 52: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix H.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Carter, 1983[37]	Acute stroke patients in a hospital setting without tumours	Cognitive skill retraining involving visual scanning and	Routine stroke program. (N=17)	• Letter cancellation test • Visual-spatial tasks

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
	or extensive bilateral damage.	visual-spatial tasks. (N=16)		matching to sample (Identifying objects)
Spitzyna, 2007 [246]	Patients with a right sided homonymous hemianopia that interfered with reading (69% of them had experienced stroke).	Reading moving text (Moving Text) that scrolled from right-to-left, daily for two four week blocks. (N=11)	Sham visual rehabilitation therapy. (N=8)	• Reading speed • Text reading speed • Single word reading speed • Eye movement task • Visual field perimetry
Modden 2012[174]	Patients with homonymous hemianopia with a posterior cerebral artery stroke. Patients were excluded if they had visual neglect eye-movement disorders, neuropsychological disorders like aphasia, dysexecutive syndromes, memory deficits, or higher order motor impairments like apraxia.	There were two different interventions: (1) Restitution training: A computer based therapy-integrated perimeter program which created the exact measurement of the individual visual field border. Target stimuli appeared in the hemianopic border zone to which the participant had to respond (intervention based on the principal of covert attention shift. (N=15) (2) Compensatory therapy: A computer based therapy which was adapted individually according to the side of the hemianopia. The therapy was using visual scanning and the participant had to respond to a target icon. (N=15)	Occupational therapy consisting of individually adapted stimulation of daily activity tasks to compensate via eye, head-, and body movements. (N=15)	• Visual field expansion (TAP* visual field - omissions) • Visual search (cancellation task of the BIT) • Reading performance (standardised texts of the Wechsler Memory Test) • Attention (alertness test (TAP Phasic Alertness) • Visual conjunction search (TAP, visual scanning) • Barthel Index

**Note. TAP=Testbatterie zur Aufmerksamkeitsprüfung (Attention test battery) Zimmermann & Fimm (2002)*

Comparison: Eye Movement Therapy (EMT) for visual field loss versus usual care/sham visual rehabilitation

Table 53: Eye Movement Therapy versus usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
						Eye Movement Therapy Mean (SD)	Usual care Mean (SD)	Effect		
Author	Design	Limitations	Inconsistency	Indirectness	Imprecision			Mean difference (95% ci)	Mean Difference (MD) (95% CI)	Confidence (in effect)
Visual scanning letter cancellation test (Better indicated by higher values)										
Carter, 1983[37]	RCT	Serious limitations(a)	No serious inconsistency	No serious indirectness	No serious imprecision	35.9 (21.3)	3.8 (13.2)	32.10 (15.96, 48.24)	MD 32.1 higher (15.96 to 48.24 higher)	Moderate
Visual-spatial tasks matching to sample (Better indicated by higher values)										
Carter, 1983[37]	RCT	Serious limitations (a)	No serious inconsistency	No serious indirectness	No serious imprecision	31 (22.8)	-3.3 (18)	34.30 (19.28, 49.32)	MD 34.3 higher (19.28 to 49.32 higher)	Moderate

[(a)] Randomization, blinding and allocation concealment not clear.

Table 54: Restitutional training / compensatory treatment vs. usual care (occupational therapy)

Quality assessment						Summary of Findings				
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Restitutional training / compensatory therapy Mean (SD)	Usual care (OT) Mean (SD)	Effect		Confidence in effect
								Mean difference (95% CI)	Mean difference (MD) (95% CI)	
Visual field enlargement (TAP, Visual Field Assessment) - Restitutional Training (follow-up 15 days; measured with: mean change scores; Better indicated by higher values)										
Modden 2012[174]	randomised trials	Serious (a)	no serious inconsistency	no serious indirectness	serious(b)	3.9 (4.9)	1.3 (4.7)	2.60 (-0.84, 6.04)	MD 2.6 higher (0.84 lower to 6.04 higher)	LOW
Visual field enlargement (TAP, Visual Field Assessment) - Compensatory Treatment (follow-up 15 days; measured with: mean change scores; Better indicated by higher values)										
Modden 2012[174]	randomised trials	Serious (a)	no serious inconsistency	no serious indirectness	serious(b)	2.9 (4.0)	1.3 (4.7)	1.60 (-1.52, 4.72)	MD 1.6 higher (1.52 lower to 4.72 higher)	LOW
BIT cancellation task - Restitutional Training (follow-up 15 days; measured with: mean change scores; Better indicated by higher values)										
Modden 2012[174]	randomised trials	Serious (a)	no serious inconsistency	no serious indirectness	serious(b)	5.3 (10.5)	2.3 (5.0)	3 (-2.89, 8.89)	MD 3 higher (2.89 lower to 8.89 higher)	LOW
BIT cancellation task - Compensatory Treatment (follow-up 15 days; measured with: mean change scores; Better indicated by higher values)										
Modden 2012[174]	randomised trials	Serious (a)	no serious inconsistency	no serious indirectness	serious(b)	5.4 (5.2)	2.3 (5.0)	3.1 (-0.55, 6.75)	MD 3.1 higher (0.55 lower to 6.75 higher)	LOW
Reading performance (Wechsler Memory Test) - Restitutional Training (follow-up 15 days; measured with: mean change scores; Better indicated by higher values)										
Modden 2012[174]	randomised trials	Serious (a)	no serious inconsistency	no serious indirectness	very serious(c)	0.9 (2.4)	0.7 (1.0)	0.2 (-1.12, 1.52)	MD 0.2 higher (1.12 lower to 1.52 higher)	VERY LOW
Reading performance (Wechsler Memory Test) - Compensatory Treatment (follow-up 15 days; measured with: mean change scores; Better indicated by higher values)										
Modden	randomised trials	Serious (a)	no serious inconsistency	no serious indirectness	very serious(c)	0.9 (1.1)	0.7 (1.0)	0.2 (-0.55, 0.95)	MD 0.2 higher (0.55 lower to	VERY LOW

Quality assessment						Summary of Findings				
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Restitutional training / compensatory therapy Mean (SD)	Usual care (OT) Mean (SD)	Effect		Confidence in effect
								Mean difference (95% CI)	Mean difference (MD) (95% CI)	
2012[174]									0.95 higher)	
Attention (TAP, Phasic Alertness) - Restitutional Training (follow-up 15 days; measured with: mean change scores; Better indicated by higher values)										
Modden 2012[174]	randomised trials	Serious (a)	no serious inconsistency	no serious indirectness	serious(b)	28.5 (56.9)	-13.3 (112.7)	41.8 (22.09, 105.69)	MD 41.8 higher (22.09 lower to 105.69 higher)	LOW
Attention (TAP, Phasic Alertness) - Compensatory Treatment (follow-up 15 days; measured with: mean change scores; Better indicated by higher values)										
Modden 2012[174]	randomised trials	Serious (a)	no serious inconsistency	no serious indirectness	serious(b)	77.8 (112.9)	-13.3 (112.7)	91.1 (10.37, 171.83)	MD 91.1 higher (10.37 to 171.83 higher)	LOW
Visual conjunction search (TAP visual scanning) - Restitutional Training (follow-up 15 days; measured with: mean change scores; Better indicated by higher values)										
Modden 2012[174]	randomised trials	Serious (a)	no serious inconsistency	no serious indirectness	very serious(c)	2.7 (5.1)	3.5 (6.8)	-0.8 (-5.10, 3.50)	MD 0.8 lower (5.1 lower to 3.5 higher)	VERY LOW
Visual conjunction search (TAP visual scanning) - Compensatory Treatment (follow-up 15 days; measured with: mean change scores; Better indicated by higher values)										
Modden 2012[174]	randomised trials	Serious (a)	no serious inconsistency	no serious indirectness	serious(b)	7.0 (5.0)	3.5 (6.8)	3.5 (-77, 7.77)	MD 3.5 higher (0.77 lower to 7.77 higher)	LOW
Extended Barthel Index - Restitutional Training (follow-up 15 days; measured with: mean change scores; Better indicated by higher values)										
Modden 2012[174]	randomised trials	Serious (a)	no serious inconsistency	no serious indirectness	serious(d)	1.5 (2.8)	1.8 (2.0)	-0.3 (-2.04, 3.50)	MD 0.3 lower (2.04 lower to 1.44 higher)	LOW
Extended Barthel Index - Compensatory Treatment (follow-up 15 days; measured with: mean change scores; Better indicated by higher values)										
Modden 2012[174]	randomised trials	Serious (a)	no serious inconsistency	no serious indirectness	serious(d)	3.3 (3.6)	1.8 (2.0)	1.5 (-0.58, 3.58)	MD 1.5 higher (0.58 lower to 3.58 higher)	LOW

[a]There was no allocation concealment and only participants were blinded.

[b] The confidence interval of the total effect ranges from improvement associated with the intervention to no effect (crossing one default MID)

[c] The confidence interval of the total effect ranges from appreciable benefit to appreciable harm (crossed two default MIDs)

[d] The confidence interval of the total effect ranges from appreciable improvement associated with usual care to no effect (crossing agreed MID -1.85)

[e] The confidence interval of the total effect ranges from appreciable improvement associated with the intervention to no effect (crossing agreed MID 1.85)

Narrative Summary

The following study is summarised as a narrative because the results were not presented in numerical data that could be included in the GRADE table:

Spitzyna et al, 2007[246] compared reading moving text to a sham visual rehabilitation in hemianopic patients (mainly stroke patients). Reading moving text induced small-field optokinetic nystagmus (OKN) and preferentially affected reading saccades into the blind field. The outcomes reported were: reading speeds, eye movements and visual field perimetry. Authors[246] reported a significant improvement in the reading speeds and associated eye movements with participants in the reading moving text group compared with the sham visual rehabilitation group but there was no change with the visual field perimetry across the groups.

10.1.1.2 Economic evidence

Literature review

No relevant economic evaluations comparing eye movement therapy for visual field loss with usual care were identified.

Intervention costs

In the absence of cost effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

The GDG considered that eye movement therapy for visual field loss would most likely be delivered by an orthoptist or an occupational therapist in the NHS and would typically consist of an initial 60 minute assessment with a 30 minute follow-up appointment every three weeks and follow-up would be required on average for 6 months. The estimated cost per hour of client contact for a band 7 orthoptist is £59[o,51] (typical salary band identified by clinical GDG members). This equates to an estimated total cost per patient of £285.

10.1.1.3 Evidence statements

Clinical evidence statement(s)

One study[37] comprising of 33 participants showed a statistically significant improvement in the visual scanning (letter cancellation) test in the eye movement therapy group compared to the usual care group (MODERATE CONFIDENCE IN EFFECT).

One study[37] comprising of 33 participants showed a statistically significant improvement in visual spatial tasks for participants who received eye movement therapy compared to the usual care group (MODERATE CONFIDENCE IN EFFECT).

<u>Visual field enlargement</u>

Restitutional training

One study[174] comprising of 15 participants in the restitutional training group and 15 control participants showed no significant improvement in visual field enlargement (as assessed by an attention visual field assessment) between restitutional training and control groups (LOW CONFIDENCE IN EFFECT).

Compensatory therapy

One study[174] comprising of 15 participants in the compensatory treatment group and 15 control participants showed no significant improvement in visual field enlargement (as assessed by an attention visual field assessment) between compensatory treatment and control groups (LOW CONFIDENCE IN EFFECT).

<u>Visual search (BIT cancellation test)</u>

Restitutional training

o Estimated based on data and methods from the Personal Social Services Research Unit 'Unit costs of health and social care' report and Agenda for Change salary band 7. Assumed that an orthoptist is costed similar to other allied health professionals.

One study[174] comprising of 15 participants in the restitutional training group and 15 control participants showed no significant improvement in visual search ability (as assessed by the BIT cancellation task) between restitutional training and control groups (LOW CONFIDENCE IN EFFECT).

Compensatory therapy

One study[174] comprising of 15 participants in the compensatory treatment group and 15 control participants showed no improvement in visual search ability (as assessed by the BIT cancellation task) between compensatory treatment and control groups (LOW CONFIDENCE IN EFFECT).

Reading performance (reading text from Wechsler Memory Test)

Restitutional training

One study[174] comprising of 15 participants in the restitutional training group and 15 control participants showed no significant improvement in reading performance (reading text from the Wechsler Memory Test) between restitutional training and control groups (VERY LOW CONFIDENCE IN EFFECT).

Compensatory therapy

One study[174] comprising of 15 participants in the compensatory treatment group and 15 control participants showed no improvement in reading performance (reading text from the Wechsler Memory Test) between compensatory treatment and control groups (VERY LOW CONFIDENCE IN EFFECT).

Attention (Phasic Alertness)

Restitutional training

One study[174] comprising of 15 participants in the restitutional training group and 15 control participants showed no significant improvement in attention control between restitutional training and control groups (LOW CONFIDENCE IN EFFECT).

Compensatory therapy

One study[174] comprising of 15 participants in the compensatory treatment group and 15 control participants showed a statistically significant improvement in attention control associated with compensatory treatment compared to usual care (LOW CONFIDENCE IN EFFECT).

Visual conjunction search (visual scanning test)

Restitutional training

One study[174] comprising of 15 participants in the restitutional training group and 15 control participants showed no significant improvement in visual conjunction search skills (assessed by a visual scanning test) between restitutional training and control groups (VERY LOW CONFIDENCE IN EFFECT).

Compensatory therapy

One study[174] comprising of 15 participants in the compensatory treatment group and 15 control participants showed no improvement in visual conjunction search skills (assessed by a visual scanning test) between compensatory treatment and control groups (LOW CONFIDENCE IN EFFECT).

Activities of daily living (Barthel Index)

Restitutional training

One study[174] comprising of 15 participants in the restitutional training group and 15 control participants showed no significant improvement in performance of activities of daily living (assessed by the Barthel Index) between restitutional training and control groups (VERY LOW CONFIDENCE IN EFFECT).

Compensatory therapy

One study[174] comprising of 15 participants in the compensatory treatment group and 15 control participants showed no improvement in performance of activities of daily living (assessed by the Barthel Index) between compensatory treatment and control groups (LOW CONFIDENCE IN EFFECT).

Economic evidence statements

No cost effectiveness evidence was identified.

10.1.2 Recommendations and link to evidence

Recommendation	**53. Screen people after stroke for visual difficulties.** **54. Offer eye movement therapy to people who have persisting hemianopia after stroke and who are aware of the condition.** **55. When advising people with visual problems after stroke about driving, consult the Driver and Vehicle Licensing Agency (DVLA) regulations.**
Relative values of different outcomes	The outcomes of interest included in the review were: reading speed and accuracy, eye movement scanning and letter cancellation. The GDG considered that the outcomes measures included in the review were of equal value, although reading speed and accuracy represents a real life task whereas scanning and letter cancellation are impairment level measures.
Trade-off between clinical benefits and harms	Homonymous hemianopia can impact on a range of activities of daily living including, reading, driving, navigation, eating, hygiene related activities, and social interaction. There are significant safety issues associated with missed diagnosis including falls, injuries and motor vehicle accidents. There is a benefit to a diagnosis of persistent homonymous hemianopia in terms of access to registration of visual impairment and subsequent access to sensory rehabilitation teams. A proportion of patients do spontaneously adapt to the impairment, but the numbers are presently unknown. Persistent (non-recovered) homonymous hemianopia can have a significant impact on quality of life. The group considered that treating this condition would provide major benefits in terms of improving quality of life for the individual patient. The GDG also believed the benefits of the intervention are significant given the risks of leaving the condition untreated. Patients with homonymous hemianopia must not drive within one year of their stroke onset. They may be able to reapply to the DVLA after one year if they can prove that they have learned to compensate for the defect. (Medical practitioners At a Glance Guide to the Current Medical Standards of Fitness to Drive, DVLA, 2011 [71]).

Economic considerations	No cost effectiveness studies were identified. Delivering eye movement therapy for visual field loss would involve some additional costs in terms of an orthoptist or occupational therapist assessment and follow-up time. The GDG considered that the additional costs would potentially be offset by the long term benefit to patients in terms of improved quality of life.
Quality of evidence	One small study by Carter, 1983 [37] examining a mixed population of patients with neglect and homonymous hemianopia, demonstrated an improvement in visual scanning strategies after intervention as measured by letter cancellation and visual spatial test and the confidence in these effects was graded as moderate. A second small study (Spitzyna, 2007) examined patients (75% of whom had a stroke) with persistent homonymous hemianopia, using a novel intervention of moving text. The authors reported a significant improvement in reading speed and eye movements but results were not presented in numerical data that could be included within the GRADE analysis. The GDG noted that the Carter Study was poorly defined in terms of patient recruitment and that it was unclear if the patients had hemianopa or visual neglect, or both, but the same intervention was used for both effectively. The GDG considered that there was insufficient evidence to reach generalised conclusions regarding efficacy related to activities of daily living, although there is some evidence regarding effectiveness for reading. The GDG considered that it was important for people who have had a stroke to be assessed for visual field defects and because of the impact this impairment has on the quality of the person's life and the serious safety issues in leaving this untreated, The GDG agreed that a strongly worded recommendation needed to be made to reflect these concerns even though the evidence was limited to one small study. It was noted that further research in this area is required.
Other considerations	The GDG were uncertain about the prevalence of homonymous hemianopia within a stroke population and requested that an additional literature search be conducted. Six studies[17;45;79; 99;92; 261] were identified which addressed prevalence, these were of varying quality, often examining a selected population within a hospital setting. On the basis of these studies, the GDG felt a prevalence of persistent homonymous hemianopia in the community was likely to be between 8 and 25%. Half of the patients within the papers reviewed were not aware that they were suffering from homonymous hemianopia. It was noted that routine screening for visual field defects was not currently universal and therefore potential patients were not identified or referred for therapy. Attention should be paid at stroke onset to eliciting visual field defects. The group considered that performing screening assessment is good practice and should be undertaken.

10.2 Diplopia or other ongoing visual symptoms after stroke

A stroke may lead to problems with eye movements which result in both eyes not working together as a pair. This can make it difficult to focus on specific things because of blurred vision as well as diplopia (or double vision) which impacts on reading, walking and performing everyday activities. Treatment can involve prisms, exercises and occlusion.

A search for systematic reviews was carried out for evidence on the management of diplopia and ongoing visual symptoms in people after stroke. No reviews were identified and therefore recommendations in this section were based on modified Delphi consensus statements which were based on recommendations from published national and international guidelines. Below we provide tables of statements that reached consensus and statements that did not reach consensus and give a summary of how they were used to draw up the recommendations. For details on the process and methodology used for the modified Delphi survey see Appendix F. This section of the Delphi survey

was aimed at Delphi panel members with the relevant experience to comment on visual impairments in stroke. Other members could opt out of this section. Therefore the response rate was lower.

10.2.1 Evidence review: How should people with visual impairments including diplopia be best managed after a stroke?

Population	Adults and young people 16 or older who have had a stroke
Components	• Continued monitoring and re-access into rehab • Long term support/care at home • Social participation activities • Carer/family support & education
Outcomes	• Patient and carer satisfaction • Quality of life • optimised strategies to minimise impairment and maximise activity/participation

10.2.2 Delphi statements where consensus was achieved

Table 55: Table of consensus statements, results and comments (percentage in the results column indicates the overall rate of responders who 'strongly agreed' with a statement and 'amount of comments' in the final column refers to rate of responders who used the open ended comments boxes, i.e. No. people commented / No. people who responded to the statement)

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
	People who have persisting double vision after stroke require a formal orthoptic assessment.	70.8	1/24 (4%) panel member commented The person who commented thought that **all other forms of visual impairment** would also **require orthoptic assessment**.

10.2.3 Delphi statement where consensus was not reached

Table 56: Table of 'non-consensus' statements with qualitative themes of panel comments

Number	Statement	Results %	Amount and content of panel comments – or themes
1.	All people who have impaired acuity, double vision or a visual field defect following a stroke require a formal ophthalmology assessment.	23.8	In round 2 - 7/24 (29%) panel members commented; 7/21(33%) in round 3 It was pointed out that **different aspects in the statement require different actions** ("Impaired acuity and double vision both require an ophthalmological diagnosis. Visual field defect after stroke is less problematic, and the diagnosis is usually known – in such cases adaptive treatments and education

Number	Statement	Results %	Amount and content of panel comments – or themes
			are the priority."). Other comments also highlighted that this is **not always needed**.
2.	People who have ongoing visual symptoms after a stroke, should be provided with information on compensatory strategies from: • Ophthalmology services • Orthoptic services • Occupational therapy services	15.7 50.0 31.5	In round 2 - 6/23 (26%) panel members commented; 9/20 (45%) in round 3 It was highlighted that it **depends on availability and on the need** ("Occupational Therapists are most likely to advise re rehabilitation and application to daily life whereas orthoptists can advise on vision strategies. Ophthalmology will A_x and R_x eye problems but perhaps not so much advise on strategies."). **One panel member** was **involved in** the development of **web-based therapies** that work by inducing compensatory eye movements
3.	People who have had a stroke and have visual impairments should be provided with contact details for the RNIB or Stroke Association for further information on visual impairments after stroke.	38.1	In round 2 - 4/23 (17%) panel members commented; 1/21 (5%) in round 3 People who have persisting **double vision** after stroke **require a formal orthoptic assessment**. It was pointed out that this should be done if **symptoms persist** and **not given routinely to everybody**.
4.	Assessment and information for registering as sight impaired or severely sight impaired should be provided by referral to an ophthalmologist.	47.6	In round 2 - 2/24 (8%) panel members commented; 5/21 (24%) in round 3 It was commented that: "All involved in stroke care should realise that **only ophthalmologists can sign the certification of visual impairment form**." Others **queried** whether an **orthoptist could also do this**.

10.2.4 Recommendations and links to Delphi consensus survey

Statements	27. People who have persisting double vision after stroke require a formal orthoptic assessment.
	56. Refer people with persisting double vision after stroke for formal orthoptic assessment.
Economic considerations	There are costs associated with a formal orthoptic assessment. The estimated cost per hour of client contact for a band 7 orthoptist is £59[p51] (typical salary band identified by clinical GDG members). There is currently a lack of convincing evidence in favour of any intervention for the treatment of diplopia after stroke. However, the GDG thought that a formal orthoptic assessment might indicate underlying individual causes that may lead to possible treatment activities. For this reason, the GDG considered the costs associated with orthoptic assessment likely to be offset by its benefits.
Other considerations	The GDG interpreted the lack of consensus as indicating no conclusive agreement could be drawn from the Delphi panel on what is beneficial for diplopia. The GDG took into account that this is a condition that would seriously affect an individual's quality of life and that it is therefore important that this is formally assessed. Even though there is not enough robust evidence to support one treatment over another for diplopia at present, the GDG thought that the results may indicate a path of treatment options based on individual need. It is also possible that a formal orthoptic assessment might indicate underlying individual causes that may lead to possible treatment activities, such as prisms or patching. The GDG also considered that that the provision of information to the person who experiences diplopia post stroke and their carer/ family is central in this process (including available treatment options). However, the GDG stressed that it is important for clinicians to keep in mind that there is currently a lack of convincing evidence in favour of any intervention. It is therefore necessary in discussions with the patient and their carers / family to be sensitive and set realistic goals.

p Estimated based on data and methods from the Personal Social Services Research Unit 'Unit costs of health and social care' report and Agenda for Change salary band 7. Assumed that an orthoptist is costed similar to other allied health professionals.

11 Swallowing

Dysphagia (difficulty swallowing) is common following stroke, occurring in up to 67% of stroke patients. Stroke patients with dysphagia have higher rates of chest infection, aspiration pneumonia, dehydration and malnutrition than stroke patients without dysphagia. The presence of dysphagia is also associated with a significantly increased risk of death, disability, length of hospital stay, and institutional care.

Symptoms and signs which may indicate the presence of dysphagia include:

- A feeling that food or liquid is sticking in the throat;
- A sensation of a foreign body or "lump" in the throat;
- A need to modify or restrict certain food types
- Drooling;
- Difficulty initiating a swallow
- Nasal regurgitation of food or drink during swallowing
- Coughing or choking during eating and drinking
- Gurgly or wet voice after swallowing
- Unexplained weight loss
- Respiratory symptoms including increasing respiratory rate and shortness of breath.

Dysphagia rehabilitation programmes use a combination of approaches aimed at either improving or compensating for the underlying disorder. Programmes may focus on strengthening muscles or on using different groups of muscles to assume the function of the damaged muscles. General dysphagia management programmes that incorporate early identification of swallowing difficulties through screening or assessment and modification of oral intake have been associated with a reduced risk of pneumonia in the acute stage of stroke.

11.1.1 Evidence review: In people after stroke what is the clinical and cost-effectiveness of interventions for swallowing versus alternative interventions / usual care to improve difficulty swallowing (dysphagia)?

Clinical Methodological Introduction	
Population:	Adults and young people 16 or older who have had a stroke
Intervention:	• Carbonated water • Frazier free water protocol • Swallowing exercises : a. effortful swallowing technique b. head-positioning c. tongue exercises d. thickened fluids/texture modification

Clinical Methodological Introduction	
	e. Mendelssohn's manoeuvre
Comparison:	• Usual care • Thickening fluids • Nil by mouth Alternative interventions • Naso-gastric feeding
Outcomes:	• Occurrence of aspiration pneumonia • Occurrence of chest infections • Reduction in hospital stay • Reduction in re-admission • Return to normal diet

11.1.1.1 Clinical evidence

Searches were conducted for systematic reviews and RCTs comparing interventions to improve swallowing for reducing dysphagia in patients with stroke. Only studies with a minimum sample size of 20 participants (10 in each arm) and including at least 50% of participants with stroke were selected. Three (3) RCTs were identified.

Table 57: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix H.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Carnaby et al, 2006[36]	Patients with stroke within the previous 7 days with a clinical diagnosis of swallowing difficulty and no history of swallowing treatment or surgery of the head or neck.	• Standard 'low intensity' swallowing therapy: appropriate dietary modification and swallowing compensation strategies, mainly environmental modifications (for example upright positioning for feeding), safe swallowing advice (for example reduced rate of eating) for 3 times per week for a month or during the hospital stay (if less than a month) (N=102) • Standard 'high-intensity' swallowing therapy: dietary modification and direct swallowing exercises (for example, effortful swallowing, supraglottic swallow technique) every working day for a month or daily for the duration of hospital stay (if less than a	Usual care: Physicians referred their patients to the speech and language therapists if they considered it to be appropriate. Treatment, if offered, consisted mainly of supervision for feeding and precautions for safe swallowing (for example, positioning, slowed rate of feeding). (N=102)	• Return to pre-stroke diet in 6 months. • Occurrence of severe chest infection

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
		month). (N=102)		
DePippo et al, 1994[63]	Acute stroke patients over 20 years old with stroke in a rehabilitation unit with no known history of significant oral or pharyngeal anomaly.	Diet control and daily reinforcement of compensatory swallowing techniques added to formal dysphagia treatment session (diet prescription, diet and compensatory swallowing technique recommendations) by a dysphagia therapist. (N=39)	Formal dysphagia treatment session (diet prescription, diet and compensatory swallowing technique recommendations) by a dysphagia therapist (N=38).	• Occurrence of pneumonia
Garon et al, 1997[89]	Patients with stroke within the last 3 weeks with a documented aspiration of thin liquids only.	Patients had all liquids thickened but were allowed free access to water (amount measured) but not with meals or for an hour after meals; no compensatory swallow techniques, direct or indirect swallow therapy or cues given. (N=10)	Patients had thickened fluids only (with meals or as requested); no compensatory swallow techniques, direct or indirect swallow therapy or cues given. (N=10)	• Occurrence of aspiration pneumonia

Comparison of behavioural interventions for dysphagia versus usual care

Table 58: Standard low intensity swallowing therapy for dysphagia versus usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
						Standard low intensity swallowing therapy Frequencies (%)	Usual care Frequencies (%)	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision			Relative Risk (95% CI)	Absolute effect (95% CI)	Confidence (in effect)
Return to pre stroke diet in 6 months										
1 Carnaby 2006[36]	RCT-single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (a)	65/102 (63.7%))	57/102 (55.9%)	1.14 (0.91 to 1.43)	78 more per 1000 (from 50 fewer to 240 more)	Moderate
Occurrence of severe chest infection										
1 Carnaby 2006[36]	RCT-single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (b)	26/102 (25.5%)	48/102 (47.1%)	0.54 (0.37 to 0.8)	216 fewer per 1000 (from 94 fewer to 296 fewer)	Moderate

(a) Confidence interval crossed one end of default MID (1.25).
(b) Confidence interval crossed one end of default MID (0.75).

Table 59: Standard high intensity swallowing therapy for dysphagia versus usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
						Standard high intensity swallowing therapy Frequencies (%)	Usual care Frequencies (%)	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision			Relative Risk (95% CI)	Absolute effect (95% CI)	Confidence (in effect)
Return to pre stroke diet in 6 months										
1 Carnaby 2006[36]	RCT- single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (a)	71/102 (69.6%)	57/102 (55.9%)	1.25 (1 to 1.54)	140 more per 1000 (from 0 more to 302 more)	Moderate
Occurrence of severe chest infection										
1 Carnaby 2006[36]	RCT- single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (b)	28/102 (27.5%)	48/102 (47.1%)	0.58 (0.4 to 0.85)	198 fewer per 1000 (from 71 fewer to 282 fewer)	Moderate

(a) Confidence interval crossed one end of MID (1.25)
(b) Confidence interval crossed one end of MID (0.75)

Table 60: Reinforcement of swallowing postures versus usual care- Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
						Reinforcement of swallowing postures (frequencies %)	Usual care (frequencies %)	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision			Relative Risk (95% CI)	Absolute effect (95% CI)	Confidence (in effect)
Occurrence of pneumonia										
1 DePippo 1994[63]	RCT	Serious limitations (a)	No serious inconsistency	No serious indirectness	Very serious imprecision (b)	2/39 (5.1%)	5/38 (13.2%)	0.39 (0.08 to 1.89)	80 fewer per 1000 (from 121 fewer to 117 more)	Very low

(a) No allocation concealment, unclear blinding
(b) Confidence interval crossed both ends of MID (0.75, 1.25)

Comparison of unlimited oral intake of water in addition to thickened liquids versus thickened liquids only

Table 61: Unlimited oral intake of water in addition to thickened liquids versus thickened liquids only - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
						Unlimited oral intake of water (plus thickened liquids) (frequencies %)	Thickened liquids only (frequencies %)	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision			Relative Risk (95% CI)	Absolute effect (95% CI)	Confidence (in effect)
Occurrence of aspiration pneumonia										
1 Garon 1997[89]	RCT-unblinded	Very serious limitations(a)	No serious inconsistency	No serious indirectness	No serious imprecision	0/10	0/10	(b)	(b)	Low

(a) Unblinded study; randomisation and allocation concealment unclear.
(b) No events experienced in any group (intervention, control) so no relative and absolute effect could be estimated.

11.1.2 Economic Literature review

One study was included that included the relevant comparison.[169] This is summarised in the economic evidence profile below (Table 62 and Table 63). See also the full study evidence tables in Appendix I.

Table 62: Standard 'low intensity' swallowing therapy versus usual care – Economic study characteristics

Study	Limitations	Applicability	Other comments
Marsh 2010[169] (UK)	Minor limitations (a)	Directly applicable (b)	The authors labelled this study as a cost-benefit analysis; however it is in fact a cost analysis taking into account initial and future costs.

(a) Effectiveness data is based on one RCT so does not reflect all the evidence in this area as the clinical review included more studies.
(b) The probability of requiring hospital or community care for chest infection was based on data not specific to people with dysphagia.

Table 63: Standard 'low intensity' swallowing therapy versus usual care – Economic summary of findings

Study	Incremental cost	Incremental effects	Net Benefit	Uncertainty
Marsh 2010[169] (UK)	saves £213 (a)	NR	NR	Threshold analysis: standard low intensity swallowing therapy is cost saving as long as probability of developing a chest infection with standard therapy is below 38%. The cost of chest infection requiring hospital admission was varied between £1,800 and £5,100. Standard low intensity swallowing therapy is cost saving as long as the cost of chest infection requiring hospital admission is above £2,000.

(a) Costs of staff time for the initial strategy, future costs of treating chest infections in hospital and community. Standard low intensity swallowing therapy is more costly initially when compared to usual care (£219 versus £59) but it is associated with lower rates of chest infections and lower cost of treating chest infections (£659 versus £ 872).

11.1.3 Evidence statements

Clinical evidence statement(s)

Standard low intensity swallowing therapy for dysphagia versus usual care

One study (Carnaby 2006[36]) comprising 204 people who have had a stroke showed that people who received a standard low intensity swallowing therapy were no more likely to return to their pre-stroke diet after 6 months than those who received usual care (moderate confidence in the effect).

One study (Carnaby 2006[36]) comprising 204 people who have had a stroke showed that there were significantly fewer people of those who received a standard low intensity swallowing therapy

experiencing chest infections compared to those who received usual care (moderate confidence in the effect).

Standard high intensity swallowing therapy for dysphagia versus usual care

One study (Carnaby 2006[36]) comprising 204 people who have had a stroke showed that people who received a standard high intensity swallowing therapy were significantly more likely to return to their pre-stroke diet after 6 months than those who received usual care (moderate confidence in the effect).

One study (Carnaby 2006[36]) comprising 204 people who have had a stroke showed that there were significantly fewer people of those who received a standard high intensity swallowing therapy experiencing chest infections compared to those who received usual care (moderate confidence in the effect).

Reinforcement of swallowing postures versus usual care

One study (DePippo 1994[63]) comprising 77 people who have had a stroke showed that people who received reinforcement of swallowing postures did not have higher rates of pneumonia compared to those who received usual care (very low confidence in the effect).

Unlimited oral intake of water in addition to thickened liquids versus thickened liquids only

One study (Garon 1997[89]) comprising 20 people who have had a stroke showed no case of aspiration pneumonia in either the group who received unlimited oral intake of water in addition to thickened liquids or the thickened liquids only group (very low confidence in the effect)

Health economic evidence statement(s)

- One directly applicable study with minor limitations showed that low intensity SLT saves around £213 per patient compared to usual care when initial costs and cost of treating chest infections are included.

11.1.4 Recommendations and link to evidence

	57. Assess swallowing in people after stroke in line with recommendations in Stroke (NICE clinical guideline 68). **58. Offer swallowing therapy at least 3 times a week to people with dysphagia after stroke who are able to participate, for as long as they continue to make functional gains. Swallowing therapy could include compensatory strategies, exercises and postural advice.** **59. Ensure that effective mouth care is given to people with difficulty swallowing after stroke, in order to decrease the risk of aspiration pneumonia.** **60. Healthcare professionals with relevant skills and training in the diagnosis, assessment and management of swallowing disorders should regularly monitor and reassess people with dysphagia after stroke who are having modified food and liquid until they are stable (this recommendation is from Nutrition support in adults [NICE clinical guideline 32]).** **61. Provide nutrition support to people with dysphagia in line with recommendations in Nutrition support in adults (NICE clinical guideline 32) and Stroke (NICE clinical guideline 68).**
Relative values of different outcomes	The outcomes reported in the studies included: return to normal diet, occurrence of chest infection and aspiration pneumonia. In the short-term the prevention of aspiration pneumonia is a critical outcome, but in the long term a return to a normal diet has a significant impact on quality of life for both patients and carers. Dysphagia may result in percutaneous endoscopic gastrostomy (PEG) feeding, which may have a significant negative impact on quality of life as well as significantly increased costs.
Trade-off between clinical benefits and harms	Untreated dysphagia could lead to serious complications including: aspiration pneumonia, dehydration and death. Normal swallowing allows people to enjoy meal times and related social interactions, and is therefore considered to be linked to an improvement in quality of life. People who are having thickened food may need assistance with oral hygiene and this should be monitored. The GDG agreed that good oral hygiene has been linked with a reduction in aspiration pneumonia and should be incorporated into any dysphagia management plan. The group noted that people with dysphagia have a higher risk of aspiration pneumonia.
Economic considerations	One directly applicable study with minor limitations showed that low intensity swallowing therapy saves around £213 per patient compared to usual care when initial costs and cost of treating chest infections are included. The GDG agreed that the cost of providing swallowing therapy for

	dysphagia compared to usual care could potentially be offset by cost savings due to reductions in chest infections and improved outcomes for patients including reduced mortality and improvement in quality of life.
Quality of evidence	The GDG considered the Carnaby study [36]to be a well conducted single centred study, which examined the effects of high and low intensity swallowing on return to pre-stroke diet at 6 months and aspiration pneumonia compared to a control group. The control group was not typical of current UK practice, where physicians only referred their patients to the speech and language therapists if they considered it to be appropriate was not typical of current UK practice. Treatment, if offered, consisted mainly of supervision for feeding and precautions for safe swallowing (for example, positioning, slowed rate of feeding). Appraisal of this study graded the results for the outcomes reported as moderate. The evidence showed that a significantly lower proportion of participants who received the swallowing therapy experienced chest infections compared to usual care group. In addition a significantly higher proportion of participants receiving the high intensity swallowing therapy returned to pre stroke diet at 6 months compared to usual care. The study was not powered to compare low against high intensity therapy, but there was consensus amongst the group that the benefit of swallowing therapy employing a full range of techniques clearly outweighed the harms and should be offered at least three times a week to patients with dysphagia. It is not possible to recommend the high intensity intervention from the evidence reviewed, but the GDG agreed that the range of swallowing therapies should be specified and that the minimum should be the low intensity therapy of at least 3 times per week, but in some circumstances the high intensity may be more appropriate for those patients who are medically stable, able to tolerate an hour of therapy each day and follow instructions/information provided. One small study by Garon[89] examined the effects of thickened fluids and free access to water on the occurrence of pneumonia but there were no episodes of pneumonia in either group. On the basis of this study, the authors reported that they allow free access to water. However, members of the GDG were aware of other studies investigating free access to water but no other RCT data was available at present. The GDG did not consider the results from this study were sufficient to recommend free access to water. There was uncertainty amongst the GDG about whether there may be potential harms but it was agreed this was an important area which requires further research.
Other considerations	The group were aware of a growing evidence base of the benefits of post-operative patients are fully hydrated in reducing length of stay in hospital. The GDG noted that patients should be weighed regularly and any weight loss needs to be explained and agreed that the problem of weight loss may be due to dysphagia, but could also be attributed to other causes such as difficulties feeding due to neglect, or upper limb weakness or depression.

12 Communication

12.1 Aphasia

Aphasia describes a language disorder that results from damage to areas of the brain responsible for different aspects of language. One or several modes of communication including comprehension and expression which involve speech, writing and gesture, may be affected. Beyond the direct impairment, aphasia impacts on many aspects of the individual's life such as relationships, social engagement and independence. It has been estimated that approximately one third of stroke survivors are affected by aphasia (Department of Health 2007).

The Speech and Language Therapist's assessment results inform the aims and objectives of targeted intervention. This will have been negotiated with the individual and as appropriate with their family or carers. Speech and Language Therapy is focused on improving an individual's ability to communicate through multiple strategies by aiming to:

• help the person to use and enhance remaining abilities.

• restore language abilities as much as possible.

• compensate for language problems by developing strategies.

• learn other methods of communicating.

• Coach others (family, health and social care staff) to learn effective communication skills to maximise the aphasic patient's competence.

A search for evidence from systematic reviews was carried out and a Cochrane systematic review (Brady et al, 2012[30]) was identified for the management of aphasia and dysarthria. This systematic review was updated and recommendations were drawn on this evidence. There was a lack of direct evidence for interventions for dysphasia, dysarthria and apraxia of speech and therefore modified Delphi statements were developed for this topic area based on recommendations in published national and international guidelines (section 12.3).

12.1.1 Evidence Review: In people who have aphasia after stroke is speech and language therapy compared to no speech and language therapy or placebo (social support and stimulation) effective in improving language/communication abilities and/or psychological wellbeing?

Clinical Methodological Introduction	
Population	Adults and young people 16 or older who have aphasia after stroke and who have been assessed as having aphasia.
Intervention	Speech and language therapy: • Any form of targeted practice tasks or methodologies with the aim of improving language or communication abilities – not necessarily provided by a professional speech and language therapist
Comparison	• No speech and language therapy • Placebo (social support and communicative stimulation): Emotional, psychological or creative interventions (such as art, dance or music), conversation or other informal, unstructured communicative interactions. This comparison does not include targeted therapeutic interventions that aim to resolve participants' expressive or receptive speech and language impairments

Clinical Methodological Introduction	
Outcomes	• Functional communication (language or communication skills sufficient to permit the transmission of message via spoken, written or non-verbal modalities, or a combination of these channels) • Formal measures of receptive language skills (language understanding) • Formal measures of expressive language skills (language production) • Overall level of severity of aphasia as measured by specialist test batteries (may include Western Aphasia Battery or Porch Index of Communicative Abilities) • Psychological or social wellbeing including depression, anxiety and distress • Patient satisfaction / carer and family views • Compliance / drop-out

12.1.1.1 Clinical Evidence Review

A search was conducted for systematic reviews comparing the clinical effectiveness of Speech and Language Therapy (SLT) with no SLT or placebo (social support and stimulation) to improve language, communication abilities and/or psychological wellbeing in adults and young people 16 or older who have had a stroke.

One Cochrane systematic review (Brady 2012[30]) that assessed the effectiveness of SLT for aphasia after stroke was identified. The Cochrane review included a total of 39 trials (RCTs). From these trials, we included 12 trials matching our protocol (**Table 64**) and we inspected an additional trial [107] from the Cochrane list of excluded trials. We deemed this trial suitable for re- inclusion. We excluded studies with Chinese language outcome measures (due to major linguistic differences) and those with an acute stroke population.

A further update search was conducted for any trial published since July 2011 which was the search cut-off date of the included Cochrane review and one study (Palmer 2012[198]) (**Table 66**) was identified.

In the Cochrane systematic review the following strategy of analysis was adopted:

- Trials were included if they reported a comparison between a group that received SLT intervention (provided either by a speech and language therapist, a trained volunteer or computer) and a group that received:
  - No SLT intervention (**Table 64**); or
  - Social support or stimulation (**Table 9**)
- Six Five trials [133 241 283 157 236] randomised participants across three or more groups (trial arms). For the purpose of meta-analysis, data from these trials were presented and pooled within paired comparisons (see GRADE tables and forest plots)
- The review presented data from these five trials [133 241 283 157 236] in paired 'sub comparisons'. For example data from Wertz 1986 were divided into two sub comparisons of (1) conventional SLT versus no SLT (Wertz 1986i [283]), (2) volunteered-facilitated SLT versus no SLT (Wertz 1986ii [283]) (**Table 64**). Other examples were ; Katz 1997i [133]; Katz 1997ii [133]; Smith 1981i [241]; Smith 1981ii [241]; Wertz 1986i [283]; Wertz 1986ii [283]
- Different measurement tools (for example, Western Aphasia Battery (WAB), Amsterdam-Nijmegan Everyday Language Test (ANELT-A), Porch Index of Communicative Abilities (PICA) amongst others) assessing a single outcome were combined and data presented in a meta-

analysis using standardised mean difference summary statistic (see GRADE Tables and forest plots)

- For SLT versus no SLT, reported follow-up assessments ranged from two months (Smania 2006 [240]) to 12 months (MacKay 1988) (see GRADE table and forest plots)
- For SLT versus social support and stimulation, reported follow-up assessments ranged from four weeks (Rochon 2005 [217]) to ten months (Hartman 1987[107])
- Non-language outcomes were also reported. These were self-reported anxiety, depression and hostility.
- In addition number of drop-outs and noncompliance with treatment were also analysed

For this review, we have included 9 trials (**Table 64**) comparing SLT to no SLT and 5 trials (**Table 9**) comparing SLT to placebo (social support and stimulation).

We have also included an additional trial (Hartman 1987 [107]) comparing conventional SLT with emotionally supportive counselling therapy (placebo) (**Table 9**). It was classified as a quasi-randomised study by the Cochrane. This study had serious study limitations due to poor allocation concealment, but we concluded that it was a randomised study and re-included it in the analysis. The study limitations were then considered in the GRADE rating (see GRADE **Table 68**).

Overall functional communication, receptive language, expressive language and severity of impairment across included trials as well as the different assessment tools used to measure these outcomes were analysed. For this reason, we have one row representing the total effect and 2 – 3 following rows for the different assessment tools used.

The evidence statements also reflect the total effects as well as the effects of the assessment tools used.

Please see Appendix M for excluded trials.

Table 64: Speech and Language Therapy (SLT) versus no SLT

Overview of included studies from the Cochrane systematic review

STUDIES	NUMBER OF PARTICIPANTS	INTERVENTION	OUTCOMES
Doesborgh 2004 [66]; Katz 1997i [133]; Katz 1997ii [133]	103 participants	Computer-mediated SLT: Improve naming using computer cueing programme; computerised language tasks using visual matching and reading comprehension.	• Functional communication • Receptive language skills • Expressive language skills • Severity of aphasia • Psychological or social wellbeing including depression, anxiety and distress • Compliance / drop-out
Jufeng 2005ii Lincoln 1984 [156]; Smania 2006 [240]; Smith 1981ii [241]; Wertz 1986i [283]	548 participants	All used conventional SLT: As chosen by each speech and language therapist.	•

STUDIES	NUMBER OF PARTICIPANTS	INTERVENTION	OUTCOMES
MacKay 1988 [163]; Wertz 1986ii [283]	179 participants	Volunteer-facilitated SLT: SLT administered by trained volunteer (family member/friend) with no previous healthcare experience.	
Smith 1981i [241]	33 participants	Intensive SLT : Type of intensive SLT not described, but 'intensive' due to number and length of sessions per week	

Table 65: Speech and Language Therapy (SLT) versus placebo (social support and stimulation)

Overview of included studies from the Cochrane systematic review and one additional study (Hartman 1987 [107]) that was excluded in the Cochrane review but added to this review

STUDIES	NUMBER OF PARTICIPANTS	INTERVENTION	SOCIAL SUPPORT AND STIMULATION*	OUTCOMES
David 1982 [56]; Elman 1999 [76]; Hartman 1987 [107]; Lincoln 1982iii [157]; Shewan 1984iii [236]	284 participants	Conventional SLT: As chosen by each speech and language therapist	Untrained volunteers received details about participants' aphasia, and were instructed to 'stimulate communication to the best of their ability. They were not given instruction in SLT techniques; participants also attended social group activities of their choice.	• Functional communication • Receptive language skills • Expressive language skills • Severity of aphasia • Psychological or social wellbeing including depression, anxiety and distress • Carer's perspective of the participant's communication • Compliance / drop-out
Rochon 2005 [217]	5 participants	Sentence-mapping SLT: 4 levels of treatment: active, subject cleft, passive, object cleft sentences	Unstructured conversation about current events; participants were given a narrative retelling task on alternate sessions	
Shewan 1984ii [236]	53 participants	Language-oriented SLT: Based on psycholinguistic (psychology of language) principles provided by speech and language	Based on stimulation orientation, providing psychological support, communication in unstructured settings carried	

STUDIES	NUMBER OF PARTICIPANTS	INTERVENTION	SOCIAL SUPPORT AND STIMULATION*	OUTCOMES
		therapists	out by nurses	
Bowen 2012[29] ACT NoW (Assessing the effectiveness of Communication Therapy in the North West)	170 participants and 135 carers	Therapy started 2 weeks after stoke and involved 22 contacts, for 18 hours (mean), delivered over 13 weeks in both hospital and community settings by qualified NHS SL therapists. (N=85)	19 contacts, for 15 hours (mean), delivered over 13 weeks by employed visitors with no professional experience of stroke or SL therapy. Visitors were trained to deliver social attention absent of any intuitive form of communication therapy or strategy. (N=85)	

***support and communicative stimulation: Provided by volunteers. They were given no guidance or instruction in SLT techniques but were provided with detailed information on their patient's communication problems and were instructed to 'stimulate communication to the best of their ability'.**

Table 66: Overview of additional RCT (Palmer 2012[198]) since the search cut-off date of the Cochrane systematic review

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Palmer 2012[198]	Participants with stroke and aphasia with word-finding difficulties as one of the predominant features; ability to repeat spoken words; no longer receiving speech and language therapy.	Usual language activities as for control group plus speech and language therapy delivered through independent use of computer program (StepbyStep; library of over 13000 language exercises) supported by a volunteer; work through exercises for at least 20 minutes 3 days a week for 5 months	Participation in activities that provide general language stimulation: attendance at communication support groups and conversation, reading and writing activities that are part of daily life	• Percentage improvement in word retrieval ability (from Object and Action Naming Battery)

Comparison: Speech and Language Therapy (SLT) versus no SLT

Table 67: Speech and Language Therapy (SLT) versus no SLT - Study references and summary of findings

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	No SLT Mean (SD)/ Frequency (%)	Standard Mean Difference (SMD)/ Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) (95% CI)	Confidence (in effect)
Functional communication (Better indicated by higher values)										
3 See sub-groups below (next 6 rows)	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	See sub-group for means	See sub-group for means	0.28 (-0.03, 0.59)	SMD 0.28 higher (0.03 lower to 0.59 higher)	Low
Functional communication - WAB (Better indicated by higher values)										
1 Katz 1997i [133]; Katz 1997ii [133]	RCT- single blind	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	Katz (i): 13.8 (5.3) Katz (ii): 13.8 (5.3)	Katz (i): 13.7 (5) Katz (ii): 12.2 (6.7)	0.14 (-0.40, 0.69)	SMD 0.14 higher (0.4 lower to 0.69 higher)	Low
Functional communication - ANELT-A (Better indicated by higher values)										
1 Doesborgh 2004 [66]	RCT- single blind	Serious limitations(d)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	34.3 (8.4)	25.5 (10.3)	0.88 (-0.10, 1.87)	SMD 0.88 higher (0.1 lower to 1.87 higher)	Low
Functional communication - Functional Communication Profile (Better indicated by higher values)										
1 Wertz	RCT- single blind	Serious limitations(a	No serious inconsistency	No serious indirectness	Serious imprecision(	Wertz (i): 59.35	Wertz (i): 55.60	0.25 (-0.16; 0.66)	SMD 0.25 higher (0.16	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	No SLT Mean (SD)/ Frequency (%)	Standard Mean Difference (SMD)/ Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) (95% CI)	Confidence (in effect)
1986i [283]; Wertz 1986ii [283]		)			b)	(19.62) Wertz (ii): 62.05 (21.83)	(19.56) Wertz (ii): 55.60 (19.56)		lower to 0.66 higher)	
Receptive language: auditory comprehension (Better indicated by higher values)										
3 See sub-groups below (next 4 rows)	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	No serious imprecision	See sub-group for means	See sub-group for means	0.10 (-0.20, 0.39)	SMD 0.1 higher (0.2 lower to 0.39 higher)	Moderate
Receptive language: auditory comprehension - PICA subtest (Better indicated by higher values)										
1 Katz 1997i [133]; Katz 1997ii [133]	RCT- single blind	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	Katz (i): 61.7 (19.8) Katz (ii): 61.7 (19.8)	Katz (i): 58.7 (25.3) Katz (ii): 57.9 (23.9)	0.15 (-0.40, 0.69)	SMD 0.15 higher (0.4 lower to 0.69 higher)	Low
Receptive language: auditory comprehension - Token Test (Better indicated by higher values)										
2 Smania 2006 [240]; Wertz 1986i [283]; Wertz 1986ii [283]	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	No serious imprecision	Smania: 18.2 (7.65) Wertz (i): 118.39 (41.95) Wertz (ii): 119.89	Smania: 14.94 (10.23) Wertz (i): 119.91 (38.48) Wertz (ii):	0.08 (-0.27, 0.43)	SMD 0.08 higher (0.27 lower to 0.43 higher)	Moderate

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	No SLT Mean (SD)/ Frequency (%)	Standard Mean Difference (SMD)/ Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) (95% CI)	Confidence (in effect)
						(45.06)	119.91 (38.48)			
Receptive language: reading comprehension (Better indicated by higher values)										
2 See sub-groups below (next 4 rows)	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	No serious imprecision	See sub-group for means	See sub-group for means	0.11 (-0.21, 0.44)	SMD 0.11 higher (0.21 lower to 0.44 higher)	Moderate
Receptive language: reading comprehension - Reading Comprehension Battery for Aphasia (Better indicated by higher values)										
1 Wertz 1986i [283]; Wertz 1986ii [283]	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	Wertz (i): 76.90 (16.97) Wertz (ii): 77.24 (20.79)	Wertz (i): 75.03 (18.06) Wertz (ii): 75.03 (18.06)	0.11 (-0.3, 0.52)	SMD 0.11 higher (0.3 lower to 0.52 higher)	Low
Receptive language: reading comprehension - PICA reading subtest (Better indicated by higher values)										
1 Katz 1997i [133]; Katz 1997ii [133]	RCT- single blind	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	Katz (i): 69.8 (22.6) Katz (ii): 69.8 (22.6)	Katz (i): 69.3 (20.2) Katz (ii): 65.1 (22.2)	0.12 (-0.42, 0.67)	SMD 0.12 higher (0.42 lower to 0.67 higher)	Low
Receptive language: gesture use - PICA Gestural subtest (Better indicated by higher values)										
2 Katz 1997i	RCT- single blind	Serious limitations(a	No serious inconsistency	No serious indirectness	Serious imprecision(	Katz (i): 79.8 (14.1)	Katz (i): 66.3 (21.9)	8.04 (1.55, 14.52)	MD 8.04 higher (1.55	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	No SLT Mean (SD)/ Frequency (%)	Standard Mean Difference (SMD)/ Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) (95% CI)	Confidence (in effect)
[133]; Katz 1997ii [133]; Wertz 1986i [283]; Wertz 1986ii [283]		)			e)	Katz (ii): 79.8 (14.1) Wertz (i): 65.32 (19.03) Wertz (ii): 62.78 (25.67)	Katz (ii): 68.30 (23) Wertz (i): 59.68 (20.98) Wertz (ii): 59.68 (20.98)		to 14.52 higher)	
Receptive language: gesture comprehension (post intervention) - Unnamed gesture comprehension assessment tool (Better indicated by higher values)										
1 Smania 2006 [240]	RCT- single blind	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	7.36 (2.17)	8.28 (1.36)	-0.92 (-2.19, 0.35)	MD 0.92 lower (2.19 lower to 0.35 higher)	Low
Receptive language: gesture comprehension (2 months follow-up) - Unnamed gesture comprehension assessment tool (Better indicated by higher values)										
1 Smania 2006 [240]	RCT- single blind	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	6.75 (2.81)	7.89 (1.17)	-1.14 (-3.23, 0.95)	MD 1.14 lower (3.23 lower to 0.95 higher)	Low
Expressive language: naming (Better indicated by higher values)										
2 See sub-groups below (next 4 rows)	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	See sub-group for means	See sub-group for means	0.2 (-0.27, 0.68)	SMD 0.2 higher (0.27 lower to 0.68 higher)	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	No SLT Mean (SD)/ Frequency (%)	Standard Mean Difference (SMD)/ Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) (95% CI)	Confidence (in effect)
Expressive language: naming - Boston Naming Test (Better indicated by higher values)										
1 Doesborgh 2004b [66]	RCT- single blind	Serious limitations(d)	No serious inconsistency	No serious indirectness	Very serious imprecision(f)	75.6 (38.7)	75.7 (36.7)	0.00 (-0.93, 0.93)	SMD 0 higher (0.93 lower to 0.93 higher)	Very low
Expressive language: naming - WAB Naming subtest (Better indicated by higher values)										
1 Katz 1997i [133]; Katz 1997ii [133];	RCT- single blind	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	Katz (i): 7 (2.4) Katz (ii): 7 (2.4)	Katz (i): 6.9 (2.8) Katz (ii): 5.5 (3.3)	0.27 (-0.27, 0.82)	SMD 0.27 higher (0.27 lower to 0.82 higher)	Low
Expressive language: naming – Object and Action Naming Battery 5 months follow-up (Mean difference in change from baseline - better indicated by higher values)										
1 Palmer 202[198]	RCT- single blind	No serious inconsistency	No serious inconsistency	No serious indirectness	Serious imprecision(b)	N=15	N=13	N/A	Mean difference from baseline 19.8 (4.4-35.2)	Moderate
Expressive language: naming - Object and Action Naming Battery 8 months follow-up (Mean difference in change from baseline - better indicated by higher values)										
1 Palmer 202[198]	RCT- single blind	No serious inconsistency	No serious inconsistency	No serious indirectness	Serious imprecision(b)	N=12	N=11	N/A	Mean difference from baseline 11.3 (-7.4-29.9)	Moderate

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	No SLT Mean (SD)/ Frequency (%)	Standard Mean Difference (SMD)/ Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) (95% CI)	Confidence (in effect)
Expressive language: general - PICA Verbal subtest (Better indicated by higher values)										
2 Katz 1997i [133]; Katz 1997ii [133]; Wertz 1986i [283]; Wertz 1986ii [283]	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(g)	Katz (i): 62.3 (22.3) Katz (ii): 62.3 (22.3) Wertz (i): 56.48 (18.29) Wertz (ii): 57.41 (20.1)	Katz (i): 58.1 (19.1) Katz (ii): 50.6 (24.5) Wertz (i): 52.8 (19.48) Wertz (ii): 52.8 (19.48)	5.28 (-1.33, 11.89)	MD 5.28 higher (1.33 lower to 11.89 higher)	Low
Expressive language: written copying - PICA Copying subtest (Better indicated by higher values)										
1 Katz 1997i [133]; Katz 1997ii [133]	RCT- single blind	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	Katz (i): 61.9 (14.8) Katz (ii): 61.9 (14.8)	Katz (i): 60.4 (19) Katz (ii): 55.4 (24.2)	3.88 (-5.75, 13.5)	MD 3.88 higher (5.75 lower to 13.5 higher)	Low
Expressive language: written (Better indicated by higher values)										
2 See sub-groups below (next 4 rows)	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	See sub-group for means	See sub-group for means	0.28 (-0.05, 0.61)	SMD 0.28 higher (0.05 lower to 0.61 higher)	Low
Expressive language: written - PICA Writing subtest (Better indicated by higher values)										

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	No SLT Mean (SD)/ Frequency (%)	Standard Mean Difference (SMD)/ Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) (95% CI)	Confidence (in effect)
1 Katz 1997i [133]; Katz 1997ii [133]	RCT- single blind	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	Katz (i): 66.9 (23.2) Katz (ii): 66.9 (23.2)	Katz (i): 59.2 (23.1) Katz (ii): 57.9 (25.3)	0.34 (-0.21, 0.89)	SMD 0.34 higher (0.21 lower to 0.89 higher)	Low
Expressive language: written - PICA Graphic (Better indicated by higher values)										
1 Wertz 1986i [283]; Wertz 1986ii [283]	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	Wertz (i): 72.64 (16.6) Wertz (ii): 74.86 (21.74)	Wertz (i): 68.57 (22.69) Wertz (ii): 68.57 (22.69)	0.25 (-0.16, 0.66)	SMD 0.16 higher (0.16 lower to 0.66 higher)	Low
Expressive language: repetition - WAB Repetition subtest (Better indicated by higher values)										
1 Katz 1997i [133]; Katz 1997ii [133]	RCT- single blind	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	Katz (i): 7.3 (2.9) Katz (ii): 7.3 (2.9)	Katz (i): 6.7 (3.4) Katz (ii): 6.1 (3.4)	0.92 (-0.76, 2.61)	MD 0.92 higher (0.76 lower to 2.61 higher)	Low
Severity of impairment: Porch Index of Communicative Ability (Better indicated by lower values)										
2 Katz 1997i [133]; Katz 1997ii [133]; Wertz 1986i [283];	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	Katz (i): 66.4 (19.4) Katz (ii): 66.4 (19.4) Wertz (i): 65.65	Katz (i): 61.3 (17.4) Katz (ii): 56.3 (20.9) Wertz (i): 61.66	0.26 (-0.07, 0.58)	SMD 0.26 higher (0.07 lower to 0.58 higher)	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	No SLT Mean (SD)/ Frequency (%)	Standard Mean Difference (SMD)/ Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) (95% CI)	Confidence (in effect)
Wertz 1986ii [283]						(24.64) Wertz (ii): 67.19 (24.64)	(21.21) Wertz (ii): 61.66 (21.21)			
Psychosocial: MAACL - Anxiety Scale (MAACL) (Better indicated by lower values)										
1 Lincoln 1984 [156]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	3 (3.2)	2.6 (2.6)	0.4 (-0.57, 1.37)	MD 0.4 higher (0.57 lower to 1.37 higher)	High
Psychosocial: MAACL - Depression Scale (MAACL) (Better indicated by lower values)										
1 Lincoln 1984 [156]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	6.9 (6.6)	6.2 (5.8)	0.7 (-1.38, 2.78)	MD 0.7 higher (1.38 lower to 2.78 higher)	High
Psychosocial: MAACL - Hostility Scale (MAACL) (Better indicated by lower values)										
1 Lincoln 1984 [156]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	2.7 (2.7)	2.8 (2.1)	0.1 (-0.9, 0.7)	MD 0.1 lower (0.9 lower to 0.7 higher)	High
Number of drop-outs (any reason)										
7 Doesborgh 2004 [66];	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	121/372 (32.50%)	122/342 (35.70%)	RR 0.92 (0.76, 1.11)	29 fewer per 1000 (from 86	High

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	No SLT Mean (SD)/ Frequency (%)	Standard Mean Difference (SMD)/ Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) (95% CI)	Confidence (in effect)
Katz 1997i [133]; Katz 1997ii [133]; Lincoln 1984 [156]; Mackay 1988 [163]; Smania 2006 [240]; Smith 1981i [241]; Smith 1981ii [241]; Wertz 1986i [283]; Wertz 1986ii [283]									fewer to 39 more)	
Non-compliance with allocated intervention (any reason)										
1 Smania 2006 [240]	RCT- single blind	Serious limitations(c)	No serious inconsistency	No serious indirectness	Very serious imprecision(b)	7/20 (35%)	5/21 (23.8%)	RR 1.47 (0.56 to 3.88)	112 more per 1000 (from 105 fewer to 686 more)	Very low

(a) Unclear randomisation; unclear allocation concealment. Limitations were considered by study weights in the meta-analysis
(b) Confidence Interval crosses one end of default MID (0.5)
(c) Unclear allocation concealment

(d) Outcome assessors not blinded
(e) Confidence Interval crosses MID (10.72)
(f) Confidence Interval crosses both ends of default MID (0.5)
(g) Confidence Interval crosses MID (9.74)
(h) Heterogeneity = 82%

Comparison: Speech and Language Therapy (SLT) versus placebo (social support and stimulation)

Table 68: Speech and Language Therapy (SLT) versus placebo (social support and stimulation) - Study references and summary of findings

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	Placebo (social support and stimulation) Mean (SD)/ Frequency (%)	Standard Mean Difference / Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) or Mean Difference (MD)(95% CI)	Confidence (in effect)
Functional communication - Functional Communication (Better indicated by higher values)										
2 4 rows)David 1982	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	See sub-group for means	See sub-group for means	0.04 (-0.22, 0.29)	SMD 0.04 higher (0.22 lower to 0.29 higher)	High
Functional communication - Functional Communication Profile (post intervention) (Better indicated by higher values)										
1 David 1982 [56]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	67 (20.3)	69.2 (22.4)	-0.10 (-0.50, 0.30)	SMD 0.10 lower (0.50 lower to 0.30 higher)	High
Functional communication – Therapy outcome measures - TOMs (post intervention) (Better indicated by higher values)										
1 Bowen	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	67 (20.3)	69.2 (22.4)	-0.13 (-0.20, 0.47)	SMD 0.13 lower (0.20 lower to	High

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	Placebo (social support and stimulation) Mean (SD)/ Frequency (%)	Standard Mean Difference / Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) or Mean Difference (MD)(95% CI)	Confidence (in effect)
2012[29] ACT NoW									0.47 higher)	
Functional communication - FCP (3-month follow-up) (Better indicated by higher values)										
1 David 1982 [56]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(a)	70.4 (19.1)	69 (21.8)	1.4 (-8.01, 10.81)	MD 1.4 higher (8.01 lower to 10.81 higher)	Moderate
Functional communication - FCP (6-month follow-up) (Better indicated by higher values)										
1 David 1982 [56]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(a)	69.3 (19.6)	68 (21.2)	1.3 (-8.07, 10.67)	MD 1.3 higher (8.07 lower to 10.67 higher)	Moderate
Receptive language: auditory comprehension - Sentence Comprehension Test (PCB) (Better indicated by higher values)										
1 Rochon 2005 [217]	RCT- single blind	Very serious limitation(b)	No serious inconsistency	No serious indirectness	Very serious imprecision(c)	72 (16)	66 (4)	6 (-12.94, 24.94)	MD 6 higher (12.94 lower to 24.94 higher)	Very low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	Placebo (social support and stimulation) Mean (SD)/ Frequency (%)	Standard Mean Difference / Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) or Mean Difference (MD)(95% CI)	Confidence (in effect)
Receptive language: auditory comprehension - Picture Comprehension Test (PCB) (Better indicated by higher values)										
1 Rochon 2005 [217]	RCT- single blind	Very serious limitation(b)	No serious inconsistency	No serious indirectness	Very serious imprecision(c)	78 (16)	70 (4)	MD 8 (-10.94, 26.94)	MD 8 higher (10.94 lower to 26.94 higher)	Very low
Receptive language: auditory comprehension - Token Test (Better indicated by higher values)										
1 [157]Rochon 2005	RCT- single blind	Very serious limitation(b)	No serious inconsistency	No serious indirectness	Very serious imprecision(c)	59 (13.93)	62.83 (16.13)	-3.83 (-18.95, 11.29)	MD 3.83 lower (18.95 lower to 11.29 higher)	Very low
Receptive language: auditory and written comprehension - PICA Gestural subtest (Better indicated by higher values)										
1 Lincoln 1982iii [157]	RCT- single blind	Serious limitation(d)	No serious inconsistency	No serious indirectness	Serious imprecision(a)	12.14 (0.8)	13.01 (0.87)	-0.87 (-1.7, -0.04)	MD 0.87 lower (1.7 to 0.04 lower)	Low
Expressive language: single words - Object Naming Test (ONT) (Better indicated by higher values)										
1	RCT- single	Serious	No serious	No serious	Serious	9.83 (6.32)	16.83 (3.76)	-7 (-11.67,	MD 7 lower	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	Placebo (social support and stimulation) Mean (SD)/ Frequency (%)	Standard Mean Difference / Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) or Mean Difference (MD)(95% CI)	Confidence (in effect)
Lincoln 1982iii [157]	blind	limitation(d)	inconsistency	indirectness	imprecision(a)			-2.33)	(11.67 to 2.33 lower)	
Expressive language: single words - Word fluency (Better indicated by higher values)										
1 Lincoln 1982iii [157]	RCT- single blind	Serious limitation(d)	No serious inconsistency	No serious indirectness	No serious imprecision	10 (5.98)	24 (6.72)	-14 (-20.35, -7.65)	MD 14 lower (20.35 to 7.65 lower)	Moderate
Expressive language: sentences - Caplan & Hanna Test: total (Better indicated by higher values)										
1 Rochon 2005 [217]	RCT- single blind	Very serious limitation(b)	No serious inconsistency	No serious indirectness	Very serious imprecision(c)	7 (2)	5 (3)	2 (-2.73, 6.73)	MD 2 higher (2.73 lower to 6.73 higher)	Very low
Expressive language: sentences - Caplan & Hanna Test: treated (Better indicated by higher values)										
1 Rochon 2005 [217]	RCT- single blind	Very serious limitation(b)	No serious inconsistency	No serious indirectness	Very serious imprecision(c)	6 (2)	3 (0.5)	3 (0.63, 5.37)	MD 3 higher (0.63 to 5.37 higher)	Very low
Expressive language: sentences - Caplan & Hanna Test: untreated (Better indicated by higher values)										

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	Placebo (social support and stimulation) Mean (SD)/ Frequency (%)	Standard Mean Difference / Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) or Mean Difference (MD)(95% CI)	Confidence (in effect)
1 Rochon 2005 [217]	RCT- single blind	Very serious limitation(b)	No serious inconsistency	No serious indirectness	Very serious imprecision(c)	1 (1)	2 (3)	-1 (-5.31, 3.31)	MD 1 lower (5.31 lower to 3.31 higher)	Very low
Expressive language: picture description - Picture description (Better indicated by higher values)										
2 Lincoln 1982iii [157]; Rochon 2005 [217]	RCT- single blind	Serious limitation(e)	No serious inconsistency	No serious indirectness	Very serious imprecision(c)	Lincoln (iii): 33.67 (22) Rochon: 34.67 (4.04)	Lincoln (iii): 30.67 (7.87) Rochon: 27 (11.31)	0.26 (-0.62, 1.15)	SMD 0.26 higher (0.62 lower to 1.15 higher)	Very low
Expressive language: picture description - Picture description with structure modelling: treated items (Better indicated by higher values)										
1 Rochon 2005 [217]	RCT- single blind	Very serious limitation(b)	No serious inconsistency	No serious indirectness	Very serious imprecision(c)	16 (2.65)	14 (4.24)	0.45 (-1.44, 2.33)	SMD 0.45 higher (1.44 lower to 2.33 higher)	Very low
Expressive language: picture description - Picture description with structure modelling: untreated items (Better indicated by higher values)										
1 Rochon 2005 [217]	RCT- single blind	Very serious limitation(b)	No serious inconsistency	No serious indirectness	Very serious imprecision(c)	18.67 (3.06)	16 (7.07)	0.41 (-1.46, 2.28)	SMD 0.41 higher (1.46 lower	Very low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	Placebo (social support and stimulation) Mean (SD)/ Frequency (%)	Standard Mean Difference / Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) or Mean Difference (MD)(95% CI)	Confidence (in effect)
									to 2.28 higher)	
Expressive language: overall spoken - PICA verbal subtest (Better indicated by higher values)										
1 Lincoln 1982iii [157]	RCT- single blind	Serious limitation(d)	No serious inconsistency	No serious indirectness	No serious imprecision	10.52 (1.2)	12.08 (0.74)	-1.56 (-2.46, -0.66)	MD 1.56 lower (2.46 to 0.66 lower)	Moderate
Expressive language: written - PICA graphic subtests (Better indicated by higher values)										
1 Lincoln 1982iii [157]	RCT- single blind	Serious limitation(d)	No serious inconsistency	No serious indirectness	Serious imprecision(a)	7.52 (1.34)	8.91 (1)	-1.39 (-2.49, -0.29)	MD 1.39 lower (2.49 to 0.29 lower)	Low
Expressive language: single words – PICA 7 month follow-up change from baseline (Better indicated by higher values)										
1 Hartman 1987	RCT- single blind	Very serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision(a)	9.341.73 (1.28)	9.111.8 (1.37)	-0.07 (-0.74, 0.60)	MD 0.07 lower (0.74 lower to 0.60 higher)	Very low
Expressive language: single words - PICA 10 months follow-up change from baseline (Better indicated by higher values)										
1	RCT- single blind	Very serious limitations(b	No serious inconsistency	No serious indirectness	Serious imprecision(	11.221.88 (1.1)	10.861.75 (1.47)	0.13 (-0.59, 0.85)	MD 0.13 higher	Very low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	Placebo (social support and stimulation) Mean (SD)/ Frequency (%)	Standard Mean Difference / Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) or Mean Difference (MD)(95% CI)	Confidence (in effect)
Hartman 1987		)			a)				(0.59 lower to 0.85 higher)	
Severity of impairment: PICA (Better indicated by lower values)										
1 Lincoln 1982iii [157]	RCT- single blind	Serious limitation(d)	No serious inconsistency	No serious indirectness	Serious imprecision(a)	10.3 (1.01)	11.43 (0.67)	-1.13 (-1.91, -0.35)	MD 1.13 lower (1.91 to 0.35 lower)	Low
Psychosocial: Communication Outcomes After Stroke scale (COAST) (6 month follow-up) (Better indicated by higher values)										
1 Bowen 2012[29] Bowen 2012	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	71 (18)	73 (18)	-2.00 (-8.59, 4.59)	MD 2.00 lower (8.59 lower to 4.59 higher)	High
Psychosocial: Carer COAST (6-month follow-up) (Better indicated by higher values)										
1 Bowen 2012[29] Bowen 2012	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	62 (21)	62 (18)	0.00 (-6.73, 6.73)	MD 0.00 (6.73 lower to 6.73 higher)	High

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	Placebo (social support and stimulation) Mean (SD)/ Frequency (%)	Standard Mean Difference / Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) or Mean Difference (MD)(95% CI)	Confidence (in effect)
Number of drop-outs for any reason										
34 Bowen 2012[29] ACT NoW David 1982 [56]; Elman 1999 [76]; Shewan 1984ii [236]; Shewan 1984iii [236]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(f)	47/221 (21.3%)	5870/206 (34%)	RR 0.69 (0.52 to 0.92)	105 fewer per 1000 (from 27 fewer to 163 fewer)	Moderate
Non-compliance with allocated intervention (any reason)										
4 Bowen 2012[29] ACT NoW David 1982 [56]; Elman	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	8/216 (3.7%)	33/193 (17.1%)	RR 0.21 (0.10 to 0.45)	135 fewer per 1000 (from 94 fewer to 154 fewer)	High

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)/ Frequency (%)	Placebo (social support and stimulation) Mean (SD)/ Frequency (%)	Standard Mean Difference / Mean difference (95% CI)	Absolute effect / Standard Mean Difference (SMD) or Mean Difference (MD)(95% CI)	Confidence (in effect)
1999 [76]; Shewan 1984ii [236]; Shewan 1984iii [236]										

(a) Confidence Interval crosses one end of default MID (0.5)
(b) Unclear randomisation, allocation concealment and blinding
(c) Confidence Interval crosses both ends of default MID (0.5)
(d) Unclear allocation concealment
(e) Unclear allocation concealment. Limitations were considered by study weights in the meta-analysis
(f) Confidence interval crosses one end of default MID (0.75)

12.1.1.2 Economic evidence

One study that included the relevant comparison was found.[29] This is summarised in the economic evidence profile below (**Table 69** and **Table 70**). See also the full study evidence table in Appendix I. **Table 69: Early speech therapy (speech therapy delivered in the hospital and continued after discharge in the community) versus no speech therapy (attention control) – Economic study characteristics**

Study	Limitations	Applicability	Other comments
Bowen[29]	Potentially serious limitations (a)	Directly applicable	Cost-effectiveness analysis based on a study included in our clinical review. Follow-up: 6 months.

(a) Utility scores were obtained at follow-up but not at baseline as the authors felt it was not feasible to do so. There was a difference in stroke severity at baseline between the two groups meaning that it cannot be assumed that the two groups would have similar utility scores. QALYs could not be calculated and the health outcome is just the difference in utility at the end of follow-up. The scores don't show how health status has changed over time as the value is from one time point (at the end of follow-up). There was a lot of missing observations for the resource use and health outcomes in both groups. This meant that using available case data could bias the results. The authors used multiple imputations to impute missing values for participants who completed scheduled follow-up for at least one of the outcome measures. This was done to reduce the impact of missing observations.

Table 70: Early speech therapy (speech therapy delivered in the hospital and continued after discharge in the community) versus no speech therapy (attention control) – Economic summary of findings

Study	Incremental cost per patient (£)	Incremental effects (QALY)	Incremental cost-effectiveness (£/QALY)	Uncertainty
Bowen 2012[29] UK NHS	110 (a,b)	0.005 (a,b,c)	£22,000 (d)	In the deterministic analysis, speech and language therapy is dominated by attention control when the incremental costs and utilities are adjusted for baseline covariates. The probability that SL therapy is cost-effective is 48% at a willingness to pay threshold of £20,000. Attention control was more cost-effective when the following variables were analysed: using trial specific costs rather than national costs, using only available case data, using alternative outcome measures rather than the EQ-5D scores. SL therapy was more cost-effective when the following variables were analysed: using an alternative regression model to estimate incremental costs and outcomes; using the TOM measure of communication outcomes measure; using the Communication Outcomes After Stroke scale (COAST) in combination with the Discrete Choice Experiment weights rather than EQ-5D

Study	Incremental cost per patient (£)	Incremental effects (QALY)	Incremental cost-effectiveness (£/QALY)	Uncertainty
				scores.

(a) Incremental values over six months as reported in the study based on the probabilistic results calculated by conducting 10,000 simulations on the estimates of incremental costs and outcomes.
(b) Includes multiple imputation values and are adjusted for baseline covariates.
(c) Based on EQ5D data was collected from study participants at the end of follow-up.
(d) Calculated by NCGC based on the costs and utility data.

12.1.1.3 Evidence statements

Clinical evidence statements

Speech and Language Therapy (SLT) versus No SLT

Functional communication

Three studies comprising 176 participants found no significant difference in functional communication between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (LOW CONFIDENCE IN EFFECT).

One study [133i 133ii] comprising 55 participants found no significant difference in functional communication (using the Western Aphasia Battery (WAB) assessment tool) between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (LOW CONFIDENCE IN EFFECT).

One study [66] comprising 18 participants found no significant difference in functional communication (using the Amsterdam-Nijmegen Everyday Language Test (ANELT-A)) between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (LOW CONFIDENCE IN EFFECT).

One study [283i 283ii] comprising 103 participants found no significant difference in functional communication (using the functional communication profile assessment tool) between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (LOW CONFIDENCE IN EFFECT).

Receptive language: auditory comprehension

Three studies comprising 191 participants found no significant difference in auditory comprehension skills between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (MODERATE CONFIDENCE IN EFFECT).

One study [133i 133ii] comprising 55 participants found no significant difference in auditory comprehension skills (using the Porch Index of Communicative Abilities (PICA)) between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (LOW CONFIDENCE IN EFFECT).

Two studies [283i 283ii 240] comprising 136 participants found no significant difference in auditory comprehension skills (using the token test assessment tool) between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (MODERATE CONFIDENCE IN EFFECT).

Receptive language: reading comprehension

Two studies comprising 158 participants found no significant difference in reading comprehension skills between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (MODERATE CONFIDENCE IN EFFECT).

One study [283i] [283ii] comprising 103 participants found no significant difference in reading comprehension skills (using the reading comprehension battery for aphasia) between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (LOW CONFIDENCE IN EFFECT).

One study [133i] [133ii] comprising 55 participants found no significant difference in reading comprehension skills (using the Porch Index of Communicative Abilities (PICA) reading subset) between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (LOW CONFIDENCE IN EFFECT).

Receptive language: gesture use

Two studies [133i] [133ii] [283i] [283ii] comprising 158 participants showed a significant difference in gesture use (using the PICA gestural subtest) in favour of the group that received speech and language therapy compared to those that did not receive speech and language therapy (No SLT) (LOW CONFIDENCE IN EFFECT)

Receptive language: gesture comprehension

One study [240] comprising 33 participants found no significant difference in gesture comprehension skills between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) post intervention (LOW CONFIDENCE IN EFFECT).

Receptive language: gesture comprehension – 2 month follow-up

One study [240] comprising 17 participants found no significant difference in gesture comprehension skills between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) at 2-month follow-up (LOW CONFIDENCE IN EFFECT).

Expressive language: naming

Two studies comprising 73 participants found no significant difference in naming skills between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (LOW CONFIDENCE IN EFFECT).

One study [66] comprising 18 participants found no significant difference in naming skills (using the Boston naming test) between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (VERY LOW CONFIDENCE IN EFFECT).

One study [133i] [133ii] comprising 55 participants found no significant difference in naming skills (using the Western Aphasia Battery (WAB) naming test) between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (LOW CONFIDENCE IN EFFECT).

Expressive language: naming at 5 and 8 months follow-up (Object and Action Naming Battery)

One study[198] comprising 28 participants found a significant improvement in naming ability (using the Object and Action Naming Battery) favouring computer based language therapy over usual care (MODERATE CONFIDENCE IN EFFECT) at 5 months but this improvement was no longer observed at the 8 month follow-up (MODERATE CONFIDENCE IN EFFECT).

Expressive language: general

Two studies [133i 133ii 283i 283ii] comprising 158 participants found no significant difference in expressive language skills (using the PICA verbal subtest) between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (LOW CONFIDENCE IN EFFECT).

Expressive language: written

Two studies comprising 158 participants found no significant difference in written expressive language skills between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (MODERATE CONFIDENCE IN EFFECT).One study [133i 133ii] comprising 55 participants found no significant difference in written skills (using the PICA copying and writing subtest) between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (LOW CONFIDENCE IN EFFECT). One study [283i 283ii] comprising 103 participants found no significant difference in written skills (using the PICA graphic subtest) between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (LOW CONFIDENCE IN EFFECT).

Expressive language: repetition

One study [133i 133ii] comprising 55 participants found no significant difference in repetition skills (using the WAB repetition subtest) between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (LOW CONFIDENCE IN EFFECT).

Severity of impairment

Two studies [133i 133ii 283i 283ii] comprising 165 participants found no significant difference in the severity of aphasia impairment (using the Porch Index of Communicative Ability) between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (LOW CONFIDENCE IN EFFECT).

Psychosocial

One study [156] comprising 137 participants found no significant difference in anxiety, depression and hostility scales between the participants that received speech and language therapy (SLT) and those that did not receive speech and language therapy (No SLT) (HIGH CONFIDENCE IN EFFECT).

Number of drop-outs (any reason)

Seven studies [66 133i 133ii 156 163 240 241i 241ii 283i 283ii] comprising 714 participants found no significant difference in the number of drop-outs between the participants that received speech and language therapy (SLT) and those that did not received speech and language therapy (No SLT) (HIGH CONFIDENCE IN EFFECT).

Non-compliance with allocated intervention (any reason)

One study[240] comprising 41 participants found no significant difference in the number of participants complying with the allocated intervention between the participants that received speech and language therapy (SLT) and those that did not received speech and language therapy (No SLT) (VERY LOW CONFIDENCE IN EFFECT).

Speech and Language Therapy (SLT) versus Placebo (social support and stimulation)

Functional communication

Two studies[29] [56] comprising 249 participants found no significant difference in functional communication (using the functional communication profile assessment tool) between the participants that received speech and language therapy (SLT) and those that received social support and stimulation (HIGH CONFIDENCE IN EFFECT) post intervention.

> One study [56] comprising 96 participants found no significant difference in functional communication (using the functional communication profile assessment tool) between the participants that received speech and language therapy (SLT) and those that received social support and stimulation (HIGH CONFIDENCE IN EFFECT) post intervention.
>
> One study [29] comprising 153 participants found no significant difference in functional communication (using the Therapy Outcome Measure Subscale (TOM)) between the participants that received speech and language therapy (SLT) and those that received social support and stimulation (MODERATE CONFIDENCE IN EFFECT) post intervention.

One study [56] comprising 73 participants found no significant difference in functional communication (using the functional communication profile assessment tool) between the participants that received speech and language therapy (SLT) and those that received social support and stimulation (MODERATE CONFIDENCE IN EFFECT) at 3 and 6-month follow-up.

Receptive language: auditory comprehension

One study [217] comprising 5 participants found no significant difference in auditory comprehension skills (using the Philadelphia comprehension battery – sentence and picture subtests) between the participants that received speech and language therapy (SLT) and those that received social support and stimulation (VERY LOW CONFIDENCE IN EFFECT).

One study [157iii] comprising 18 participants found no significant difference in auditory comprehension skills (using the token test) between the participants that received speech and language therapy (SLT) and those that received social support and stimulation (VERY LOW CONFIDENCE IN EFFECT).

Receptive language: other

One study [157iii] comprising 18 participants showed a significant difference in auditory and written comprehension skills (using the PICA gestural subtest) in favour of the participants that received social support and stimulation compared to those that received SLT (LOW CONFIDENCE IN EFFECT).

Expressive language: single words

One study [157iii] comprising 18 participants showed a significant difference in naming skills (using the Object Naming Test (ONT)) in favour of the participants that received social support and stimulation compared to those that received SLT (LOW CONFIDENCE IN EFFECT).

One study [157iii] comprising 18 participants showed a significant difference in naming skills (using the word fluency test) in favour of the participants that received social support and stimulation compared to those that received SLT (MODERATE CONFIDENCE IN EFFECT).

Expressive language: single words (follow-up measures at 7 and 10 months)

One study [107] comprising 60 participants found no significant difference in expressive language skills between the participants that received speech and language therapy (SLT) and those that received social support and stimulation at 7 and 10 months follow-up (VERY LOW CONFIDENCE IN EFFECT).

Expressive language: sentence production

One study [217] comprising 5 participants found no significant difference in overall sentence production (using the Caplan & Hanna test) between the participants that received speech and language therapy (SLT) and those that received social support and stimulation (VERY LOW CONFIDENCE IN EFFECT).

One study [217] comprising 5 participants showed a significant difference in sentence production (using treated items from the Caplan & Hanna test) in favour of the participants that received speech and language therapy (SLT) compared to those that received social support and stimulation (VERY LOW CONFIDENCE IN EFFECT).

One study [217] comprising 5 participants found no significant difference in sentence production (using untreated items from the Caplan & Hanna test) between the participants that received speech and language therapy (SLT) and those that received social support and stimulation (VERY LOW CONFIDENCE IN EFFECT).

Expressive language: picture description

Two studies [157iii] [217] comprising 23 participants found no significant difference in picture description tasks between the participants that received speech and language therapy (SLT) and those that received social support and stimulation (VERY LOW CONFIDENCE IN EFFECT).

One study [217] comprising 5 participants found no significant difference in picture description tasks with structure modelling (treated and untreated items) between the participants that received speech and language therapy (SLT) and those that received social support and stimulation (VERY LOW CONFIDENCE IN EFFECT).

Expressive language: overall spoken

One study [157iii] comprising 18 participants showed a significant difference in overall spoken test (using the PICA verbal subtest) in favour of the participants that received social support and stimulation compared to those that received SLT (MODERATE CONFIDENCE IN EFFECT).

Expressive language: written

One study [157iii] comprising 18 participants showed a significant difference in written skills (using the PICA graphic subtest) in favour of the participants that received social support and stimulation compared to those that received SLT (LOW CONFIDENCE IN EFFECT).

Severity of impairment

One study [157iii] comprising 18 participants showed that participants that received social support and stimulation were significantly less impaired as a result of aphasia (using the shortened PICA) compared to those that received SLT (LOW CONFIDENCE IN EFFECT).

Psychosocial: Communication Outcomes after Stroke scale (COAST)

One study [29] comprising 117 participants found no significant difference in the Communication Outcomes After Stroke scale (COAST)) between the participants that received speech and language therapy (SLT) and those that received social support and stimulation (HIGH CONFIDENCE IN EFFECT) at 6-month follow-up.

Psychosocial: Carer Communication Outcomes after Stroke scale (COAST)

One study [29] comprising 129 participants found no significant difference in the Carer Communication Outcomes After Stroke scale (COAST) between the participants that received speech and language therapy (SLT) and those that received social support and stimulation (HIGH CONFIDENCE IN EFFECT) at 6-month follow-up.

Number of drop-outs (any reason)

Four studies [29,56 76 236ii 236iii] comprising 427 participants showed that participants who received SLT were significantly less likely to drop-out compared to those who received social support and stimulation (MODERATE CONFIDENCE IN EFFECT).

Non-compliance with allocated intervention (any reason)

Four studies [29,56 76 236ii 236iii] comprising 409 participants showed that participants who received SLT were significantly more compliant with the allocated intervention compared to those who received social support and stimulation (MODERATE CONFIDENCE IN EFFECT).Economic evidence statements

A cost-effectiveness study directly applicable and with potentially serious limitations shows that the incremental cost-effectiveness ratio of speech and language therapy compared to other interventions (attention control) is around £22,000 per QALY gained. However there is a high uncertainty around this estimate.

12.2 Dysarthria

Dysarthria is motor speech disorder, characterised by slow slurred, imprecise speech and quiet vocal volume. The common effect of these symptoms is an impact on intelligibility, making communication difficult. This in turn can affect social interaction, employment and feelings of social stigmatisation[65].

12.2.1 Evidence Review: In people after stroke is speech and language therapy compared to social support and stimulation effective in improving dysarthria?

Clinical Methodological Introduction	
Population	Adults and young people 16 or older who have had a stroke.
Intervention	Speech and language therapy: • Any form of targeted practice tasks or methodologies with the aim of improving language or communication abilities
Comparison	• Social support and communicative stimulation: Emotional, psychological or creative interventions (such as art, dance or music), conversation or other informal, unstructured communicative interactions. This comparison does not include targeted therapeutic interventions that aim to resolve participants' expressive or receptive speech and language impairments
Outcomes	• Measures of functional communication • Formal measures of receptive language skills (language understanding) • Formal measures of expressive language skills (language production) • Psychological or social wellbeing including depression, anxiety and distress • Frenchay Dysarthria Assessment. • Measures of articulation (range, speed, strength, and co-ordination) • Perceptual measures of voice and prosody (for example, Vocal Profile Analysis) • Acoustic measures (for example, fundamental frequency, pitch perturbation (jitter), amplitude perturbation (shimmer), etc. as measured by, for example, computerised sound spectrography)

12.2.1.1 Clinical Evidence Review

A search was conducted for systematic reviews comparing the clinical effectiveness of Speech and Language Therapy (SLT) with social support and stimulation to improve dysarthria in adults and young people 16 or older who have had a stroke.

One Cochrane systematic review (Sellars 2005 [235]) that assessed the effectiveness of speech and language therapy for dysarthria was identified (**Table 71**). Trials were considered if they reported a comparison between a group that received SLT intervention and a group that received (1) no SLT intervention and (2) an intervention undertaken by non-SLT personnel, for example, delivered by volunteers (i.e., SLT versus non-SLT). Sixteen trials were considered for inclusion but rejected from the review.

A further systematic update search was conducted for any trial published since September 2004 which was the search cut-off date of the included Cochrane review and one study (Bowen 2012 [29] ACT NoW study) was identified.

Table 71: Overview of additional RCT (Bowen 2012 [29]) since the search cut-off date of the Cochrane systematic review

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Bowen 2012[29] ACT NoW (Assessing the effectiveness of Communication Therapy in the North West)	One hundred and seventy adults with aphasia, dysarthria or both admitted to hospital with stroke. Sixty-six participants had dysarthria. Participants ranged in age from 32 to 97 years (mean 70 years)	Therapy started 2 weeks after stoke and involved 22 contacts, for 18 hours (on average), delivered over 13 weeks in both hospital and community settings by qualified NHS SL therapists. Intervention was tailored to individual needs and abilities (Outcome information available on N=33 participants with dysarthria)	19 contacts, for 15 hours (on average), delivered over 13 weeks by employed visitors with no professional experience of stroke or SL therapy. Visitors were trained to deliver social attention which involved general conversation, involving the patient in various activities (reading, watching television or videos, playing a selection of games) (Outcome information available on N=27 participants with dysarthria)	• Functional communicative ability on the Therapy Outcome Measure activity subscale (TOM)

Comparison: Speech and Language Therapy (SLT) versus social support and stimulation

Table 72: Speech and Language Therapy (SLT) versus social support and stimulation - Study references and summary of findings

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	SLT Mean (SD)	Social support and stimulation Mean (SD)	Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
Functional communication – Therapy Outcome Measure activity subscale (TOM) (6-month follow-up) (Better indicated by higher values)										
1 Bowen 2012 [29]	RCT- single blind	No serious limitation	No serious inconsistency	Serious indirectness(a)	Very serious imprecision(b)	3.1 (1.4)	3.1 (1.7)	0.00 (-0.80, 0.80)	MD 0.00 (0.80 lower to 0.80 higher)	Very low

(a) A mixed population of consisting of people with dysarthria alone and also people with dysarthria as well as aphasia
(b) Confidence Interval crosses both ends of default MID (0.5)

12.2.1.2 Economic evidence

Literature review

No relevant economic evaluations were included in the review. The economic analysis in the ACT NoW study[29] was set up to cover both people with aphasia and dysarthria; however, since the majority of the patients in the economic analysis had aphasia (90%), this study was included in the review for aphasia (see 12.1.1) but considered not applicable to people with dysarthria (39% of the population in the paper had either both dysarthria and aphasia or dysarthria alone) as the treatment would be different from the one used in the study.

Economic considerations

The estimated cost of a band 6 speech and language therapist is £47 per hour of client contact[q].

12.2.1.3 Evidence statements

Clinical evidence statements

Speech and Language Therapy (SLT) versus social support and stimulation

Functional communication: Therapy Outcome Measure activity subscale (TOM)

One study [29] comprising 66 participants with dysarthria found no significant difference in functional communication (using the Therapy Outcome Measure activity subscale (TOM)) between the participants that received speech and language therapy (SLT) and those that received social support and stimulation at 6-month follow-up (VERY LOW CONFIDENCE IN EFFECT).

Economic evidence statements

- No cost effectiveness evidence was identified.

12.2.2 Recommendations and ink to evidence

Aphasia and Dysarthria

	62. Screen people after stroke for communication difficulties within 72 hours of onset of stroke symptoms. **63. Each stroke rehabilitation service should devise a standardised protocol for screening for communication difficulties in people after stroke.** **64. Provide appropriate information, education and training to the multidisciplinary stroke team to enable them to support and communicate effectively with the person with communication difficulties and their family or carer.** **65. Speech and language therapy for people with stroke should be led and supervised by a specialist speech and language therapist working collaboratively with other appropriately trained people – for example,**

q Estimated based on data and methods from Personal Social Services Research Unit 'Unit costs of health and social care' report and Agenda for Change salary band 6[50] (typical salary band identified by clinical GDG members).

	speech and language therapy assistants, carers and friends, and members of the voluntary sector. **66. Provide opportunities for people with communication difficulties after stroke to have conversation and social enrichment with people who have the training, knowledge, skills and behaviours to support communication. This should be in addition to the opportunities provided by families, carers and friends.** **67. Speech and language therapists should assess people with limited functional communication after stroke for their potential to benefit from using a communication aid or other technologies (for example, home-based computer therapies or smartphone applications).** **68. Provide communication aids for those people after stroke who have the potential to benefit, and offer training in how to use them.** **69. Tell the person with communication difficulties after stroke about community-based communication and support groups (such as those provided by the voluntary sector) and encourage them to participate.** **70. When persisting communication difficulties are identified at the person's 6-month or annual stroke reviews, refer them back to a speech and language therapist for detailed assessment, and offer treatment if there is potential for functional improvement.** **71. Make sure that all written information (including that relating to medical conditions and treatment) is adapted for people with aphasia after stroke. This should include, for example, appointment letters, rehabilitation timetables and menus.**
Relative values of different outcomes	The GDG recognised that outcomes in speech and language therapy could look at both impairment and function. While improvement in function is the ultimate aim, small targeted studies may detect impairment changes more easily. Some members of the GDG questioned the responsiveness of the Functional communicative ability on the Therapy Outcome Measure activity subscale TOM. (ACT NOW) to reflect clinically meaningful change, but were not aware of any publications reporting responsiveness with this instrument. It was queried whether steps could be considered equal (i.e. a change from 0 to 1 is functionally the same change as one from 3 to 4). It was felt that it was not clear how you moved from one point to another within the scale and it may be open to interpretation. The Communication Outcomes After Stroke scale (COAST) which was developed for use in the ACT NoW study has reported validity and reliability data for use in the study. The GDG agreed the way this had been developed was reasonable.
Trade-off between clinical benefits and harms	The GDG were not aware of any potential harms from language based therapies. However the importance of regular review to reassess people with communication difficulties was noted, and the GDG agreed the guidance of 6 month and then annual review as given in the National Stroke Strategy should be recommended.[61]
Economic considerations	The GDG noted that SLT is currently routinely provided in the NHS to people with aphasia. The cost of a band 6 or 7 speech and language therapist is £47 or £57 per

	hour of client contact. The ACT NoW study showed that there is a high uncertainty over the cost effectiveness of speech and language therapy compared to attention control. In this study patients received speech and language therapy on average for 18hrs and 22 contacts over 13 weeks per patient. This was considered to be a low level of intensity by the GDG. At this level of intensity there is uncertainty that it is cost-effective over and above paid visitors and a higher level of intensity could make the intervention more cost-effective. Based on these considerations and on the level of improvement of patients who received the intervention, the GDG felt that the benefits of SLT are likely to outweigh the costs. There are high costs associated with providing communication aids as some software are expensive (up to £2,000) and training people to use them would require around three months. However other applications are available from smartphones and they are not very expensive. The GDG has decided that given the potential high costs involved, communication aids should be provided only to those people who are likely to benefit.
Quality of evidence	The Cochrane systematic review included studies if they reported a comparison between a group that received SLT intervention and a group that received no SLT or social support or stimulation. Eight studies that matched the protocol were included for SLT versus no SLT and five for SLT versus social support or stimulation plus an additional study not included in the Cochrane review. The majority of studies were found to be small, poorly described, old and estimated effects for most of the outcomes specified were non-significant. The confidence in the effect of specified outcomes ranged from very low to high with the majority being low. Outcomes were downgraded for study limitations, inconsistency and imprecision. No significant difference was found for any of the functional communication outcomes in both arms. Speech and Language Therapy (SLT) showed significant improvement in receptive language compared to no SLT while social support and communicative stimulation showed significant improvement in receptive language, expressive language and in reducing the severity of impairment. The improvements seen with social support and communicative stimulation were all from one study (Lincoln 1982iii [157]) comprising of 18 participants. The GDG noted that the result should be read with caution as it lacks generalisability as it is not a true representation of the aphasic population. The GDG noted that current practice has changed since many of the studies were published, and that the details of the intervention was not provided or poorly described in many of the studies. This made it difficult for the GDG to draw meaningful conclusions. The group did agree that the results highlight the benefits of supported communication and it was agreed that SLT has become broader than is reflected in the studies and would now include support and stimulation. A more recent well conducted study was the ACT NOW study delivered on average 18hrs of therapy over 13 weeks in both hospital and community settings. The interventions were largely delivered by band 6 speech and language therapists, although patients improved, a similar level of gain was achieved by paid visitors. There were 6 elements to the speech and language therapy interventions: assessment, information provision, provision of communication materials, carer contact, indirect contact (including disc with clinical teams and goal setting), and direct contact (including impairment, activity and participation skills). However, the outcome measure focussed on functional communication which was only one aspect of the Speech and Language Therapist's intervention. The GDG noted that the trial was conducted on participants soon after onset of stroke (2weeks), and that this does not reflect all stages of stroke recovery. People may make change at a later stage of recovery and this study does not reflect the entire scope of SLT input. The ACT NoW study was a well conducted study of speech and language therapy

	compared with paid visitors, early after stroke. The GDG noted a number of areas that might influence clinical interpretation including the relatively low dose of therapy and the power of the study. Dysarthria In the ACTNoW study 39% of the participants had dysarthria', and 29% had both aphasia and dysarthria, and a sub analysis for the therapy outcome measure activity subscale outcome (TOM) was conducted. No significant difference was found between the SLT group and the social support and stimulation group. The GDG discussed the use of a functional intervention in this population and agreed that for this subgroup the intervention would initially be impairment based and functional communication therapy would be given later in the person's rehabilitation. It was felt that this analysis did not provide any useful information to provide specific guidance for this group.
Other considerations	The GDG was aware that practice has changed in the past 30 years. The findings relating to the benefits of social support interventions should not be overlooked in delivering services. The increasing use of communication tools such as computer and smart phone technologies was also noted. The GDG were aware of the College of Speech and language therapists' aphasia commissioning document, which provides an overview of the various therapies. [223]. The group expressed concern that the ACT NoW study should not be over interpreted and stressed the central role of Speech and Language therapy in the organisation, assessment and treatment of communication difficulties over the whole stroke pathway, should be recognised. It was agreed that it was important to start therapy as soon as possible after stroke and that an assessment of communication should be undertaken within 72 hours of admission and this was currently usual practice. It was acknowledged that screening would be undertaken on admission to an acute unit; however no particular screening tool could be recommended. The studies have emphasised the importance of social support and providing an enriched environment in delivery of SLT and the GDG acknowledged trained volunteers play an important role in providing this. The GDG agreed that therapy should be managed and led by a specialist speech and language therapist. The patient representative highlighted that for people with dysarthria guidance on help with movement of the tongue is important and this could only be provided a SLT therapist. The GDG also noted that the number of drop outs and non-compliance to allocated intervention was lower in the SLT group compared to social support and intervention. The GDG also considered the qualitative component of the ACT NoW study. In this section participants' and carers' views and experiences of SLT or visitor support where evaluated. The GDG felt that it was important that participants / carers valued outside contact regardless of whether a SLT or visitor. Personal qualities of SLT/visitors were highlighted by participants (for example putting people at ease, ability to make participants feel important etc.). Members of the GDG felt that it was also important that patients experienced different aspects of their meetings with SLTs/visitor as meaningful, such as those who had the SLT highlighted explicit strategies that were helpful to build confidence; whereas those who had visitors valued the social engagement processes and everyday 'practice' aspect of this contact. It was therefore noted that opportunities to engage with communication partners should play a part in the rehabilitation of people who have had a stroke and have language impairment and that professionals should aim to provide such contacts.

12.3 Speech and language therapies for dysarthria and apraxia of speech

There was a lack of direct evidence for dysphasia, dysarthria and apraxia of speech (sections 12.2 and 12.3). Therefore recommendations in these sections were based on modified Delphi consensus statements (based on recommendations in published national and international guidelines). Below we provide tables of statements that reached consensus and statements that did not reach consensus and give a summary of how they were used to draw up the recommendations. For details on the process and methodology used for the modified Delphi survey see Appendix F.

12.3.1 What interventions improve communication in people dysphasia, dysarthria and apraxia of speech?

Population	Adults and young people 16 or older who have had a stroke and who have speech and language impairments
Components	8. Assessment 9. Speech and language therapies 10. Communication aids
Outcomes	11. Quality of life 12. Communication skills 13. Social participation

12.3.2 Delphi statements where consensus was achieved

Table 73: Table of consensus statements, results and comments (percentage in the results column indicates the overall rate of responders who 'strongly agreed' with a statement and 'amount of comments' in the final column refers to rate of responders who used the open ended comments boxes, i.e. No. people commented / No. people who responded to the statement)

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
	For all people with speech and language impairments the Speech and Language Therapist needs to explain and discuss the impairment with the person who has had a stroke/family/carers/treatment team and teach them how to manage the condition.	78.6	3/28 (11%) panel members commented One person commented that this **does not need to be carried out** by a **speech and language therapist** as long as it is under the **guidance** of one. **Carer involvement** was also highlighted. One person expressed surprise that **Communication Support Services** were **not included in the whole** speech and language **section**.
1.	Early after stroke the person with a speech and language impairment should be facilitated to communicate everyday needs and wishes, and supported to understand and	93.1	4/29 (14%) panel members commented It was commented that there are

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
	participate in decisions around, for example, medical care, transfer to the community, and housing. This may need alternative and augmentative forms of communication.		**interactions with cognition and emotion** and therefore input from other MDT members may be needed. It was stated that AAC may be low tech and **simple paper and pen** or **higher tech I-pad apps** could be used. One comment was that this **depends** on the person's individual **assessment**, **readiness** to participate and his/her stated **goals**. **Training for** some members of **the MDT** may also be necessary.
2.	People who have had a stroke and who have persisting speech and language deficits should be assessed for alternative means of communication (gesture, drawing, writing, use of communication aids).	73.1	2/26 (8%) panel members commented One person stated that **mixing** people with **language** and those with **speech impairments** together is **not appropriate** in this statement. The other person thought that this **statement was too obvious** to be useful.
3.	The impact of speech and language impairments on life roles for example family, leisure, work, etc. should be assessed and possible environmental barriers (for example signs, attitudes), should be addressed, jointly with the MDT.	81.5	3/27 (11%) panel members commented One person pointed out that this would **not happen** in the **acute stage** of rehabilitation. Another person thought that it **should also involve family** and friends, employers and relevant other agencies A third person indicated that **'addressed'** was **not clear**.

12.3.3 Delphi statement where consensus was not reached

Table 74: Table of 'non-consensus' statements with qualitative themes of panel comments

Number	Statement	Results %	Amount and content of panel comments – or themes
1.	The key aim of speech and language therapy early after stroke should be to	55.0	In round 2 - 17/27 (63%) panel members commented; 11/20(55%)

Number	Statement	Results %	Amount and content of panel comments – or themes
	minimise the communication impairment.		in round 3 Panel members thought that there are **many facets** to the aims of speech and language therapy that were **not captured** by this statement. Such as: To deal with the **impact** of the communication impairment To **assess and educate** regarding the extent of the difficulty To **address** the person's **confidence**, To **enhance skills** of **communication partners** To **remove barriers** to communication Extract: "This can be very broadly defined. Minimising the communication impairment is not necessarily just reducing the actual impairment. It may be providing advice and information which enhances understanding and indirectly minimises the problem, it may be using strategies to facilitate communication, it may be providing facilitated emotional support to reduce trauma which can enhance communication."
2.	The list of approaches that may be used with a patient who is dysphasic: Picture cards Drawings Sound Boards Writing Phonological sound cueing Modelling words Sentence completion Melodic intonation therapy Neurolinguistic approach Computerised approach	 36.8 42.1 12.5 33.3 27.7 22.2 33.3 5.8 27.7 38.8	In round 2 - 20/27 (74%) panel members commented; 11/19(58%) in round 3 Some **further approaches** were suggested: Talking mats Semantic cueing Gesture Cognitive neuropsychological approaches Constraint induced therapy (which uses picture cards) Augmentative and alternative communication One person highlighted that any approach needs to be **evidence based**. It was also highlighted that the statement **implies** a **focus on**

Number	Statement	Results %	Amount and content of panel comments – or themes
			language impairment rather than focus on the skills and competence of the person who has dysphasia and those in their communicative environment. This panel member suggested the **following approaches** to do this: **Information and support** for the person and their family/friends/service providers (and also about language strengths) **Training** of conversation **partners** Access to **peer support** Others **specifically favoured impairment-based approaches**. It was highlighted that this would **vary from person to person** ("The Speech and Language Therapist would make a communication book tailored to the individual rather than alphabet chart and/or talking mats to aid discussion").
3.	The list of approaches that might be used with a patient who is dysarthric: Oral muscular exercises Monitoring rate of speech production Pausing Alphabet supplementation	 21.7 34.7 26.0 27.2	In round 2 - 12/24 (47%) panel members commented; 14 commented in round 3 (free text prompt) The **following approaches** were suggested: **Initiation of vocalisation** (exercises for articulation) **Coordination** between **breathing and speech** (breathing support exercises) **Sustaining voice** during speech production **Pacing** **Gesture** **Advice** about condition, and **training of conversation partners** **Computer** therapy **Writing / drawing** **Augmentative and alternative communication** **Compensatory slowing of speech** rate with exaggerated articulation

Number	Statement	Results %	Amount and content of panel comments – or themes
			One person highlighted that this should be a focused approach **based on assessment** ("the system that is most compromised would be targeted for example respiration, palatal movement, voice, articulation, rate of speech, phrasing, intonation").
4.	List of approaches that might be used with a patient who has dysarthrophonia: Biofeedback Voice amplifier Intense therapy to increase loudness	 12.5 11.7 0.0	In round 2 - 9/23 (39%) panel members commented; 7/17(41%) in round 3 No clear approaches were suggested. It was stated that this **depends on** the patient's **presentation and severity**. It was also highlighted that this is a **rare problem** and that there is **no evidence** to support a particular approach.
5.	The list of approaches that might be used with a patient who has articulatory dyspraxia: Cognitive linguistic therapy Repetitive drills Auditory input/analysis Automatic speech Singing Phonemic cueing Word imitation Computer programmes Varley approach AAC (Augmentative and Alternative Communication) reading aloud Distraction practice with feedback Phoneme manipulation tasks Segment by Segment approach SWORD (computer software) Prosodic therapy	 20.0 41.6 33.3 38.4 8.3 16.6 8.3 38.4 27.2 18.1 11.1 9.0 18.1 27.2 25.0	In round 2 - 16 panel members commented (free text prompt); 8/14(57%) in round 3 **No further approaches** were suggested and it was highlighted that any approach needs to be **evidence based**.
6.	Any patient with severe articulation difficulties (<50% intelligibility) reasonable cognition and language function should be assessed for and provided with alternative or augmentative communication aids.	61.1	In round 2 - 3/25 (12%) panel members commented; 3/18(17%) in round 3 It would **depend on stage of rehab**, success of rehabilitation and prognosis. One person **objected to a level (i.e. below 50% intelligibility) being**

Number	Statement	Results %	Amount and content of panel comments – or themes
			stated ("… as it may be different for each patient and intelligibility may depend on familiarity with the patient.

12.3.4 Recommendations and links to Delphi consensus survey

Statements	28. For all people with speech and language impairments the Speech and Language Therapist needs to explain and discuss the impairment with the person who has had a stroke/family/carers/treatment team and teach them how to manage the condition. 29. Early after stroke the person with a speech and language impairment should be facilitated to communicate everyday needs and wishes, and supported to understand and participate in decisions around, for example, medical care, transfer to the community, and housing. This may need alternative and augmentative forms of communication. 30. People who have had a stroke and who have persisting speech and language deficits should be assessed for alternative means of communication (gesture, drawing, writing, use of communication aids). 31. The impact of speech and language impairments on life roles for example family, leisure, work, etc. should be assessed and possible environmental barriers (for example signs, attitudes), should be addressed, jointly with the MDT.
	72. Help and enable people with communication difficulties after stroke to communicate their everyday needs and wishes, and support them to understand and participate in both everyday and major life decisions. **73. Ensure that environmental barriers to communication are minimised for people after stroke. For example, make sure signage is clear and background noise is minimised.**
Considerations	The GDG agreed that support and information for the patient and their carer was extremely important, but also that good communication skills are required by all of the multidisciplinary rehabilitation team. The speech and language therapist has a role to educate and provide training to all of the team in order to ensure that appropriate methods of communicating with the person are used, and that there is greater awareness of environmental factors, such as noise, signs and notices within the rehabilitation unit that could impact on the person's ability to communicate. No consensus was achieved on specific forms of therapy to offer to people with other forms of speech and language impairment, however the GDG agreed that the recommendations made from the review of people with aphasia could apply to all people with communication

	difficulties, and the preferred approach to adopt would be determined through a detailed assessment by the therapist and the needs and wishes of the patient. The use of alternative methods of communication aids such as technologies via computers and smartphones was acknowledged, and it was agreed the usage of these is likely to increase. However these would not be suitable for all people and use of drawing and writing down information such as appointment letters, rehabilitation timetables etc. should be provided to those that need them.

12.4 Intensity of speech and language therapy

12.4.1 Evidence review: In people after stroke with communication difficulties what is the clinical and cost-effectiveness of intensive speech therapy versus standard speech therapy?

Clinical Methodological Introduction	
Population	Adults and young people 16 or older who have had a stroke and have communication difficulties
Intervention	Intensive speech therapy: • aphasia therapy, • constraint induced aphasia therapy (Any study including more intensive versus less intensive speech therapy)
Comparison	• Less speech therapy • No therapy
Outcomes	Any outcome reported in the papers. Examples include: • Functional Assessment of Communication Skills for Adults (ASHA FACS) • Boston Naming Test • Western Aphasia Battery • Stroke Dyphasia Index • McKenna Graded Naming Test

12.4.1.1 Clinical evidence review

Searches were conducted for systematic reviews and RCTs that compared the effectiveness of intensive speech therapy to less speech therapy or no therapy to improve speech and language function in adults and young people 16 or older after stroke. Eight (8) RCTs were identified. **Table 75** summarises the population, intervention, comparison and outcomes for each of the studies.

Table 75: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix H.

AUTHOR	POPULATION	INTERVENTION	COMPARISON	OUTCOME
Bakheit, 2007[13]	First time stroke patients (mean days	Five 1-hourly speech therapy sessions a	Less speech therapy (i.e. the same as	• Western Aphasia Battery

AUTHOR	POPULATION	INTERVENTION	COMPARISON	OUTCOME
	post stroke onset: 31) with a score of <93.8 on Western Aphasia Battery.	week for 12 weeks, targeted at improving understanding and expression of spoken and written language, including picture/object selection, naming objects, describing and recognising associations between items, facilitating expression of feelings and opinions, improving communication skills, using gestures and non-verbal communication, using communication aids and equipment (part of multidisciplinary rehabilitation) (Mean amount 4.3 hours (SD 1.0) per week achieved). (N=51)	provided to intervention group but only for two 1-hour sessions per week; actual mean amount achieved 1.6 hours (SD 0.5) per week). (N=46)	
Bowen 2012 [29] ACT NoW (Assessing the effectiveness of Communication Therapy in the North West)	One hundred and seventy adults with aphasia or dysarthria admitted to hospital with stroke. Participants ranged in age from 32 to 97 years (mean 70 years) and 56% were men. Almost all had aphasia (90%).	Therapy on average started 2 weeks after stoke and involved 22 speech and language therapy contacts, for 18 hours (mean), delivered over 13 weeks in both hospital and community settings. (N=85)	Attention Control: An average of 19 visitor contacts, for a mean of 15 hours. Visitors did not provide therapy or any communication strategies. Visitors had excellent social skills and general competency and were trained to deliver social attention absent of any intuitive form of communication therapy or strategy. (N=85)	• Therapy Outcome Measure activity subscale (TOM) • Communication Outcomes After Stroke scale (COAST) • Carers' Communication Outcomes After Stroke scale (COAST)
Denes, 1996[59]	Patients with stroke (mean months post stroke onset; 3) with global aphasia with lesion restricted to left hemisphere.	Individual speech therapy sessions (total mean number: 130 (range 94-160)) of 45-60 minutes each over a mean of 6 months (range 5.2-7 months) including conversational setting, using speaking, gesturing, facial expression.	Less intensive speech therapy: mean 60 (range 56-70) individual speech therapy sessions of 45-60 minutes each over a mean of 6 months (range 5.2-7 months) including conversational setting, using speaking, gesturing, facial	• Aachener Aphasia Test (AAT) – 5 Subtests- Token Test, Repetition, Written Language, naming, Comprehension and Profile Level

AUTHOR	POPULATION	INTERVENTION	COMPARISON	OUTCOME
		(N=8)	expression. (N=9)	
Doesborgh, 2004 [67]	Chronic stroke patients (at least 11 months post stroke) aged 20 – 86 years old, with semantic (as assessed by the Semantic Association Test and the Psycholinguistic Assessment of Language Processing in Aphasia - PALPA) and phonological deficits (as measured by the Aachen Aphasia Test – AAT Repetition subtest). However people who were assessed as having 'global aphasia' or 'recovered or no aphasia' according to the AAT were excluded.	Individual multicue treatment (computer programme for word finding) total duration 10 - 11 hours in sessions of 30 - 45 minutes each with a frequency of two to three times a week in a period of approximately 2 months. (N=9)	No therapy for 6 - 8 weeks. (N=10)	• Boston Naming Test (BNT) • Amsterdam Nijmegan Everyday Language Test, scale A (ANELT-A).
Hartman, 1987[107]	First stroke (1 month post stroke onset) patients with lesion affected to left hemisphere and with functionally normal hearing and vision.	Individual conventional speech therapy including language drills, home practice, auditory stimulation at single-word and phrase level, follow spoken commands, reading, repetition, sentence completion, cueing strategies, twice weekly for 6 months. (N=30)	Unstructured conversation-based counselling/support focused on problems of everyday life; encouraging independent problem-solving by patient/family, twice weekly for 6 months. (N=30)	• Porch Index of Communicative Ability (PICA)
Katz, 1997[133]	Chronic stroke patients (at least 1 year post stroke) with aphasia subsequent to a single, left hemisphere, thromboembolic infarct and no language treatment during the 3 months before entry into the study.	Individual computer-provided reading treatment for chronic aphasic adults. (N=21)	No therapy. (N=15)	• The Porch Index of Communicative Ability (PICA) • Western aphasia Battery (WAB) Aphasia Quotient (AQ)
Lincoln, 1984 [156]	Acute stroke (1st or later time) patients. Patients with very mild aphasia or severe	Individual two 1-hour speech therapy sessions per week (no specific type of	No speech therapy (controls offered treatment at week 34). (N=164)	• Porch Index of Communicative Ability

AUTHOR	POPULATION	INTERVENTION	COMPARISON	OUTCOME
	dysarthria were excluded.	therapy was included; therapists organised their own form of treatment) from week 10 post-stroke to week 34. (N=163)		(PICA) • Functional Communication Profile (FPA)
Wertz, 1986[283]	Acute first time stroke (2-24 weeks post stroke) male veteran patients 75 years or under with a left hemispheric lesion	Individual speech therapy administered by a speech therapist for 8-10 hours/week for 12 weeks, after then no treatment was given. (N=38) Speech therapy administered at home: trained family member or friend administered 8-10 hours/week for 12 weeks, after then no treatment was given. (N=43)	No therapy for 12 weeks (after that speech therapist administered 8-10 hours/week for 12 week.) (N=40)	• Porch Index of Communicative Ability (PICA)

Comparison: Intensive speech therapy versus less intensive speech therapy or nothing

Table 76: Intensive speech therapy versus less intensive speech therapy - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Intensive speech therapy Mean (SD)	Less intensive therapy Mean (SD)	Relative Mean difference (95% CI)	Absolute	Confidence (in effect)
Aachener Aphasia Test (AAT) - token test (6 months follow-up) (Better indicated by higher values)										
1 Denes 1996 [59]	RCT	Serious limitations (a)	No serious inconsistency	No serious indirectness	No serious imprecision	11.4 (11.6)	5.2 (7.8)	6.2 (3.32, 15.72)	MD 6.2 higher (3.32 lower to 15.72 higher)	Moderate
Aachener Aphasia Test (AAT)- repetition (6 months follow-up) (Better indicated by higher values)										
1 Denes 1996 [59]	RCT	Serious limitations (a)	No serious inconsistency	No serious indirectness	Very serious imprecision (B)	8.9 (7.7)	6.1 (6.1)	2.8 (-3.86, 9.46)	MD 2.8 higher (3.86 lower to 9.46 higher)	Very low
Aachener Aphasia Test (AAT)- written language (6 months follow-up) (Better indicated by higher values)										
1 Denes 1996 [59]	RCT	Serious limitations (a)	No serious inconsistency	No serious indirectness	No serious imprecision	11 (9.8)	2.1 (3.1)	8.9 (1.81, 15.99)	MD 8.9 higher (1.81 to 15.99 higher)	Moderate
Aachener Aphasia Test (AAT)-Naming (6 months follow-up) (Better indicated by higher values)										
1	RCT	Serious	No serious	No serious	Serious	10.2 (9.9)	4.5 (4.2)	5.7 (-1.69,	MD 5.7	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Intensive speech therapy Mean (SD)	Less intensive therapy Mean (SD)	Relative Mean difference (95% CI)	Absolute	Confidence (in effect)
Denes 1996 [59]		limitations (a)	inconsistency	indirectness	imprecision (c)			13.09)	higher (1.69 lower to 13.09 higher)	
Aachener Aphasia Test (AAT)-Comprehension (6 months follow-up) (Better indicated by higher values)										
1 Denes 1996 [59]	RCT	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	12.6 (15.2)	2.3 (3.8)	10.3 (-0.52, 21.12)	MD 10.3 higher (0.52 lower to 21.12 higher)	Low
Aachener Aphasia Test (AAT)-Profile level (6 months follow-up) (Better indicated by higher values)										
1 Denes 1996 [59]	RCT	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	10 (8.6)	4.3 (3.8)	2.7 (-0.76, 12.16)	MD 2.7 higher (0.76 lower to 12.16 higher)	Low
Western Aphasia Battery (2 months follow-up) (Better indicated by higher values)										
1 Bakheit 2007 [13]	RCT- single blinded	Serious limitations(d)	No serious inconsistency	No serious indirectness	No serious imprecision	63.1 (13.5)	63.2 (13.5)	-0.1 (-5.48, 5.28)	MD 0.1 lower (5.48 lower to 5.28 higher)	High
Western Aphasia Battery (3 months follow-up) (Better indicated by higher values)										

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Intensive speech therapy Mean (SD)	Less intensive therapy Mean (SD)	Relative Mean difference (95% CI)	Absolute	Confidence (in effect)
1 Bakheit 2007 [13]	RCT- single blinded	Serious limitations(d)	No serious inconsistency	No serious indirectness	Serious imprecision (e)	67.7 (13.4)	69.2 (13.4)	-1.5 (-6.84, 3.84)	MD 1.5 lower (6.84 lower to 3.84 higher)	Low
Western Aphasia Battery (6 months follow-up) (Better indicated by higher values)										
1 Bakheit 2007 [13]	RCT- single blinded	Serious limitations(d)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	68.6 (15.4)	71.4 (15.4)	0.4 (-0.16, 0.96)	MD 2.8 lower (8.94 lower to 3.34 higher)	Low

[a] Allocation concealment and blinding of outcome assessors not reported.
[b] Confidence interval crossed both ends of default MID.
[c] Confidence interval crossed one end of default MID.
[d] Unclear randomization.

Table 77: Intensive speech therapy versus no therapy - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
						Intensive speech therapy	No therapy	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Mean (SD)	Mean (SD)	Mean difference (95% CI)	Mean Difference (95% CI)	Confidence (in effect)
Boston Naming Test (BNT) (2 month follow-up) (Better indicated by higher values)										
1 Doesborgh 2004 [67]	RCT	Serious limitations(a)	No serious inconsistency	No serious indirectness	Very serious imprecision(b)	75.6 (38.7)	75.7 (36.7)	-0.1 (-35.26, 35.06)	MD 0.1 lower (35.26 lower to 35.06 higher)	Very low
Amsterdam Nijmegen Everyday Language Test ANELT-A (2 month follow-up) (Better indicated by higher values)										
1 Doesborgh 2004 [67]	RCT	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	34.3 (8.4)	25.5 (10.3)	8.8 (0.16, 17.44)	MD 8.8 higher (0.16 to 17.44 higher)	Low
Porch Index of Communicative ability (PICA) more intensive versus no treatment (26 week follow-up) (Better indicated by higher values)										
1 Katz 1997 [133]	RCT	Serious limitations(d)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	66.4 (19.4)	61.3 (17.4)	5.1 (-7.0, 17.2)	MD 5.1 higher (7 lower to 17.2 higher)	Low
Porch Index of Communicative ability (PICA) : less intensive versus no treatment (26 week follow-up) (Better indicated by higher values)										
1 Katz 1997 [133]	RCT	Serious limitations(d)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	26.3 (20.9)	61.3 (17.4)	-5.0 (-17.88, 7.88)	MD 5 lower (17.88 lower to 7.88 higher)	Low

Quality assessment						Summary of findings				
						Intensive speech therapy Mean (SD)	No therapy Mean (SD)	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision			Mean difference (95% CI)	Mean Difference (95% CI)	Confidence (in effect)
Western Aphasia Battery: more intensive versus no treatment (26 week follow-up) (Better indicated by higher values)										
1 Katz 1997 [133]	RCT	Serious limitations(d)	No serious inconsistency	No serious indirectness	Very serious imprecision(b)	73.6 (22.6)	72.2 (23.7)	1.40 (-14, 16.8)	MD 1.4 higher (14 lower to 16.8 higher)	Very low
Western Aphasia Battery: less intensive versus no treatment (26 week follow-up) (Better indicated by higher values)										
1 Katz 1997 [133]	RCT	Serious limitations(d)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	63.4 (28.5)	72.2 (23.7)	-8.8 (-26.35, 8.75)	MD 8.8 lower (26.35 lower to 8.75 higher)	Low
Porch Index of Communicative Ability (PICA) (1 month follow-up after lesion onset) (Better indicated by higher values)										
1 Hartman 1987 [107]	RCT	Serious limitations(e)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	9.34 (3.28)	9.11 (3.82)	0.23 (-1.74, 2.2)	MD 0.23 higher (1.74 lower to 2.2 higher)	Low
Porch Index of Communicative Ability (PICA) (10 month follow-up after lesion onset) (Better indicated by higher values)										
1 Hartman 1987 [107]	RCT	Serious limitations(e)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	11.22 (2.88)	10.86 (4.02)	0.36 (-1.57, 2.29)	MD 0.36 higher (1.57 lower to 2.29 higher)	Low

[(a)] Blinding of outcome assessors not reported.
[(b)] Confidence interval crossed two ends of default MID.
[(c)] Confidence interval crosses one end of default MID.
[(d)] Details of blinding, randomisation and allocation concealment not reported.
[(e)] Allocation concealment not reported.

Table 78: Early intensive speech therapy (speech therapy delivered in the hospital and continued after discharge in the community) versus no speech therapy (attention control)

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Early intensive speech therapy Mean (SD)	No speech therapy Mean (SD)	Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
Therapy Outcome Measure activity subscale (6-month follow-up) (Better indicated by higher values)										
1 Bowen 2012 [29]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(a)	3.3 (1.4)	3.0 (1.6)	0.30 (-0.18, 0.78)	MD 0.3 higher (0.18 lower to 0.78 higher)	Moderate
Communication Outcomes After Stroke scale (COAST) (6 month follow-up) (Better indicated by higher values)										
1 Bowen 2012 [29]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	71 (18)	73 (18)	-2.00 (-8.59, 4.59)	MD 2.00 lower (8.59 lower to 4.59 higher)	High
Carer Communication Outcomes After Stroke scale (Carer COAST) (6 month follow-up) (Better indicated by higher values)										
1 Bowen 2012 [29]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	62 (21)	62 (18)	0.00 (-6.73, 6.73)	MD 0.00 (6.73 lower to 6.73 higher)	High

(c) Confidence Interval crosses one end of default MID (0.5)

Narrative summaries

The following studies are summarised as a narrative because the results were not presented in numerical data that could be included in the GRADE table:

One study of moderate risk of bias(Lincoln et al, 1984)[156] using the PICA and the Functional Communication Programme (FCP) showed improvement in both “standard speech therapy” group and “more speech therapy” group with no significant differences in language recovery between the two groups during treatment and at 34-week post-treatment.

One study of high risk of bias (Wertz et al, 1986)[283] using the PICA percentile suggested that clinic treatment for aphasia was efficacious and delaying/deferring treatment for 12 weeks did not compromise ultimate improvement. Results of home treatment did not differ from those of clinic treatment or deferred treatment.

12.4.1.2 Economic evidence

One study was included that included the relevant comparison[169].This is summarised in the economic evidence profile below (Table 79 and Table 80). See also the full study evidence tables in Appendix I.

Table 79: Enhanced versus standard speech therapy – Economic study characteristics

Study	Limitations	Applicability	Other comments
Marsh 2010[169] (UK NHS)	Potentially serious limitations (a)	Directly applicable	Based on the RCT by Bakheit et al 2007[13] included in our clinical review. Usual SLT defined as 2 hours a week for 12 weeks (in practice was 0.57 hours per week). Enhanced SLT defined as 2 hours a week for 12 weeks (in practice was 1.6 hours per week). The original RCT compared enhanced SLT also with intensive SLT (defined as 5 hours a week for 12 weeks, in practice was 3 hours per week); however intensive SLT had no significant effect over and above enhanced SLT, therefore intensive SLT was not considered in the economic analysis (it would be dominated by enhanced SLT).

(a) The conversion of WAB test scores into QALY gains was based on a number of assumptions. For example, it assumed that the WAB test is comparable to the Aphasia test and that both scales have a similar distribution. The WAB test is scored out of 1 to 100, while the aphasia test is scored between 0 and 20. Issues around translation aphasia scales to the Barthel index which measures function. The effectiveness data used in the analysis is based on one RCT; however the NCGC clinical review has identified additional relevant studies.

Table 80: Enhanced versus standard speech therapy – Economic summary of findings

Study	Incremental cost (£)	Incremental effects (QALYs)	ICER (£/QALY)	Uncertainty
Marsh 2010[169] (UK NHS)	844 (a)	0.057 (b)	14,807	The percentage improvement in WAB test following enhanced SLT was varied between 70% and 80%. Enhanced SLT remained cost-effective as long as the improvement was above 72%. The change in QALY gain was varied between 0.040 and 0.058. Enhanced SLT remained cost-effective as long as the incremental QALY gain was above 0.042.

(a) 2009 UK pounds. Costs incorporated: community SLT costs (band 7). Standard SLT cost was calculated as 6.9 hours per patient over 12 weeks. Enhanced SLT cost was calculated as 19.3 hours per patient over 12 weeks.

(b) The improvement in WAB test scores (from baseline to 24 weeks) was calculated and converted to aphasia test scores. These scores were then translated to the Barthel index. The QALY gain was obtained by mapping from the Barthel index to EQ5D using a linear regression analysis reported in a paper by Exel et al (2004).[271]

12.4.1.3 Evidence statements

Clinical evidence statements

One study[59] comprising of 17 participants found the more intensive speech intervention was associated with a statistically significant improvement in the following subsets of Aachener Aphasie Test compared with the less intensive intervention at 6 months follow-up:

- token test (MODERATE CONFIDENCE IN EFFECT)
- written language (MODERATE CONFIDENCE IN EFFECT)

One study[59] comprising of 17 participants found no significant difference between the more intensive speech group and the less intensive group at 6 months follow-up at the following subsets of Aachener Aphasie Test:

- repetition (VERY LOW CONFIDENCE IN EFFECT)
- naming (LOW CONFIDENCE IN EFFECT)
- comprehension (LOW CONFIDENCE IN EFFECT)
- profile level (LOW CONFIDENCE IN EFFECT)

One study[13] comprising of 97 participants found no significant difference in Western Aphasia Battery score between the intensive speech group and less intensive group at the end of 2, 3 and 6 months follow-up (MODERATE, LOW and MODERATE CONFIDENCE IN EFFECT, respectively).

One study[67] comprising of 19 participants found no significant difference in the Boston Naming Test between the intensive speech group and the no therapy group at 2 months follow-up (VERY LOW CONFIDENCE IN EFFECT).

One study[67] comprising of 19 participants found that the participants received more intensive speech therapy showed a statistically significant improvement in the Amsterdam Nijmegan Everyday Language Test compared with the no therapy group at 2 months follow-up (LOW CONFIDENCE IN EFFECT).

One study[133] comprising of 36 participants found no significant difference between the more intensive speech group and the no therapy group at 6 months follow-up on the following outcomes:

- Porch Index of Communicative Ability (PICA) (LOW CONFIDENCE IN EFFECT)
- Western Aphasia Battery (LOW CONFIDENCE IN EFFECT)

One study[133] comprising of 36 participants found no significant difference between the less intensive group and the no therapy group at 6 months follow-up on the following outcomes:

- Porch Index of Communicative Ability (PICA) (VERY LOW CONFIDENCE IN EFFECT)
- Western Aphasia Battery (LOW CONFIDENCE IN EFFECT)

One study[107] comprising of 60 participants found no significant difference in the Porch Index of Communicative Ability (PICA) between the more intensive speech group and the no therapy group at 1 and 10 months follow-up after lesion onset (LOW CONFIDENCE IN EFFECT).

One study [29] comprising 153 participants found no significant difference in the Therapy Outcome Measure Subscale (TOM) between the early intensive speech therapy group and the no therapy group at 6-month follow-up (MODERATE CONFIDENCE IN EFFECT)

One study [29] comprising 117 participants found no significant difference in the Communication Outcomes After Stroke scale (COAST) between the early intensive speech therapy group and the no therapy group at 6-month follow-up (HIGH CONFIDENCE IN EFFECT)

One study [29] comprising 129 participants found no significant difference in the Carer Communication Outcomes After Stroke scale (carer COAST) between the early intensive speech therapy group and the no therapy group at 6-month follow-up (HIGH CONFIDENCE IN EFFECT)

Economic evidence statements

One directly applicable study[169] with potentially serious limitations showed that enhanced speech therapy is cost-effective compared to standard speech therapy. Enhanced speech therapy is more costly but also more effective than standard speech therapy and the ICER is below the £20,000/QALY threshold (£14,807 per QALY gained). These results were sensitive to the improvement in WAB test and to the QALY gain achieved with enhanced therapy.

12.4.2 Recommendations and link to evidence

	74. Refer people with suspected communication difficulties after stroke to a speech and language therapist for detailed analysis of speech and language impairments and assessment of their impact. **75. Speech and language therapists should:** • **provide direct impairment-based therapy for communication impairments (for example, aphasia or dysarthria)** • **help the person with stroke to use and enhance their remaining language and communication abilities** • **teach other methods of communicating, such as gestures, writing and using communication props** • **coach people around the person with stroke (including family members, carers and health and social care staff) to develop supportive communication skills to maximise the person's communication potential** • **help the person with aphasia or dysarthria and their family or carer to adjust to a communication impairment** • **support the person with communication difficulties to rebuild their identity** • **support the person to access information that enables decision-making.**
Trade-off between clinical benefits and harms	The GDG agreed that it was unlikely that there were any significant harms associated with this form of therapy provided patient expectations were kept realistic, a focus remained on participation, and the patient, family and friends were supported to manage any persisting disability. It was felt that an improvement in the ability to communicate would have a significant impact in terms of quality of life for the patient with stroke.
Economic considerations	The GDG noted that speech therapies are currently routinely offered in the UK NHS to stroke patients with aphasia. More intensive therapy would be associated with increased personnel costs. One economic evaluation[169] based on an RCT included in our review showed that enhanced speech therapy (which was 1.6 hours a week for 12 weeks) is

	more costly but also more effective than standard speech therapy (which was 0.57 hours a week for 12 weeks) and the ICER is below the £20,000 per QALY threshold, therefore this would be considered cost-effective. However, intensive speech therapy (which was 3 hours per week for 12 weeks) was not included in the formal analysis since in the RCT this was more costly and not more effective than enhanced speech therapy. Intensive speech therapy is therefore not cost-effective.
Quality of evidence	The studies should be considered as feasibility studies due to the small sample size. It was noted that they were under powered. One study showed that more intensive speech therapy was associated with an improvement in token test and written language as assessed by Aachener Aphasie Test at 6 months follow-up compared to less intensive speech therapy (Denes[59]). Confidence in the effect shown for these outcomes was graded as moderate. The GDG considered that the populations included in the trials did not reflect those who would be seen in clinical practice, many of whom would have had speech problems for a significantly longer time. In studies of intensity in the ACTNoW study the GDG agreed the evidence suggests that greater intensity when compared to social support without direct speech and language therapy resulted in greater benefit, although this was not statistically significant. The GDG agreed that the question still to be answered was whether more intense speech and language therapy delivered by more skilled staff would deliver greater benefit. What the ACT NoW study adds is the value of appropriately trained paid visitors to aid the recovery of functional communication after stroke.
Other considerations	The included studies looked at more intensive speech therapy compared to less intensive and it was the view of the GDG that none of the studies presented were particularly focussed on intensity. Three studies included intervention arms that were only short sessions 2-3 times per week (Doesborgh 2004, Hartman 1987, Lincoln 1984[67,107,156]) the GDG agreed that 18 hours and 22 contacts over 13 weeks delivered in the ACT NoW study was not particularly intensive. The group also noted that the intervention was delivered two weeks after stroke, and thought that providing SLT this early after stroke would often not be an appropriate time. There was a discussion in the GDG about the nature of intensity in speech and language therapy, and it was felt that operational definitions of intensity need to be agreed. The GDG noted that all therapies were provided in one-to-one sessions and considered this was appropriate for this type of rehabilitation. The GDG also recognised that many people with aphasia also benefit from speech therapy in groups to enhance functional communication and confidence. Further research is required that considers over 8 hours of language therapy a week reflecting the amount of therapy delivered by the Wertz study[283]. The GDG acknowledged the standard speech therapy of 5x45mins per week. The group felt that this to be the minimum but were aware that this is not considered standard care. The assessment of language deficits and therapy tailored to restore those deficits should be conducted by specialist speech and language therapists. The approach taken for each individual patient will depend on the profile of deficits and therefore a generic treatment cannot be recommended. However for people with aphasia or dysarthria the GDG

	recognised the use of impairment based therapy to help restore speech or language.

12.5 Listener advice

Aphasia can impact on a person's ability to understand and to express language through a range of modalities including speech, writing, drawing and gesture making communication difficult for the individual who has had a stroke and the communication partner. Social isolation is arguably the most devastating consequence of aphasia. It is therefore important that families/carers of the stroke patient as key communication partners are actively involved in aphasia rehabilitation programmes. Speech and Language Therapy aims to address aphasia rehabilitation using a supported communication approach which includes listener advice and multifunctional skills to facilitate communication.

Key components of listener advice training involve some of the following:

- Use of and encouragement of multi-modal communication i.e. writing, drawing, gesture, speech, augmentative and alternative communication aids
- Simplification of language by using short, uncomplicated sentences.
- Facilitation of comprehension skills by checking that the message is understood. This may require repetition
- Writing down key words to clarify meaning as needed.
- Minimising distractions whenever possible.
- Encouraging engagement of the person with aphasia in conversations.
- Maintaining a natural conversational manner appropriate for an adult.
- Avoiding correcting the person's speech or interrupting
- Allowing the person plenty of time to talk.
- Encouraging conversational turn taking
- Asking for and valuing the opinion of the person with aphasia, especially regarding family matters.

12.5.1 What listener advice skills/training or information would help family members /carers improve communication in people with aphasia after stroke?

Clinical Methodological Introduction	
Population	Families and carers of adults and young people 16 or older with aphasia after stroke
Intervention	Listener advice skills/training or information
Comparison	Usual care or nothing, sham or alternative interventions
Outcomes	• Any outcome reported in the paper • Quality of life

12.5.1.1 Clinical evidence review

Searches were conducted for systematic reviews and RCTs comparing the effectiveness of listener advice skills/training or information with usual care, sham or alternative interventions that would aid

family members/carers improve communication in people with aphasia after stroke. Two RCTs were identified.

Table 81 summarises the population, intervention and outcomes of each of the studies included in the evidence review.

Table 81: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix H.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOME
Kagan, 2001[127]	At least one year post stroke patients with moderate-to-severe aphasia.	Conversation with trained volunteer; "Supported Conversation for adults with Aphasia": for example keeping talk as natural as possible, avoiding being patronising, ensuring understanding, allowing person to express knowledge, thoughts and feelings, verifying, using gesture, writing and drawing. (N=20)	Conversation with untrained volunteer (N=20)	• Measure of Skill in Providing Supported Conversation for Adults with Aphasia (MSCA) • Measure of Participation in Conversation for Adults with Aphasia (MPCA)
Worrall, 2000[288]	Patients with chronic aphasia due to stroke (at least 12 months post-onset) in language dominant hemisphere.	Functional communication therapy programme ("Speaking Out") delivered by trained volunteers in patient's home; focusing on strategies to improve communication activities (, for example paying bills directly from bank account, using multi-trip bus tickets) for 10 weeks. (N=6)	Non-verbal recreational programme for 10 weeks. (N=8)	• Western Aphasia Battery (WAB), • American Speech-Language Hearing Association Functional Assessment of Communication Skills (ASHA FACS) • Communication Effectiveness Index (CETI) • Functional Communication Therapy Planner (FCTP) • Short Form-36 (SF-36).

Comparison: Listener advice skills/training or information versus usual care, nothing, sham or alternative interventions for stroke rehabilitation

Table 82: Listener advice skills/training or information versus usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Listener advice Mean (SD)	Usual care Mean (SD)	Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
Measure of Skill (of listener) in providing Supported Conversation for Adults with Aphasia (acknowledge competence) (Post-test) (Better indicated by lower values)										
1 Kagan et al, 2001[127]	RCT- quasi-randomised single blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	No serious imprecision	2.6 (0.7)	1.5 (0.8)	1.1 (0.63,1.57)	MD 1.1 higher (0.63 to 1.57 higher)	Moderate
Measure of Skill (of listener) in providing Supported Conversation for Adults with Aphasia (reveal competence) (Post-test) (Better indicated by lower values)										
1 Kagan et al, 2001[127]	RCT- quasi-randomised single blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	No serious imprecision	2.7 (0.6)	0.7 (0.4)	2.0 (1.68, 2.32)	MD 2 higher (1.68 to 2.32 higher)	Moderate
Measure of Participation (of person with aphasia) in Conversation for Adults with Aphasia (interaction: social connection) (Post-test) (Better indicated by higher values)										
1 Kagan et al, 2001[127]	RCT- quasi-randomised single blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision (b)	2.6 (9)	2.2 (9)	0.4 (-0.16, 0.96)	MD 0.4 higher (0.16 lower to 0.96 higher)	Low
Measure of Participation (of person with aphasia) in Conversation for Adults with Aphasia (transaction: exchange of content) (Post-test) (Better indicated by lower values)										
1	RCT – quasi-	Serious	No serious	No serious	No serious	2.7 (8)	2.0 (8)	0.7 (0.20,	MD 0.7	Moderate

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Listener advice Mean (SD)	Usual care Mean (SD)	Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
Kagan et al, 2001 [127]	randomised single blinded	limitations (a)	inconsistency	indirectness	imprecision			1.20)	higher (0.2 to 1.2 higher)	

[(a)] Unclear randomization process.
[(b)]Confidence interval crossed one default MID.

Narrative summary

The following study is summarised as a narrative because the results were not presented in numerical data that could be included in the GRADE table:

One matched-pair single-blinded randomised study (Worrall et al)[288] reported that there was a statistically significant improvement on the Western Aphasia Battery in those who received a 10-week functional communication therapy (Speaking Out) programme delivered by trained volunteers, compared to those who received usual care with recreational activities/no treatment. There were no significant differences in any of the functional communication measures. A positive mean change of 29.3 (SD=19.3) on the General Health scale of the aphasic person's SF-36 in one group was observed and there was a statistically significant negative mean change of 18.1 (SD=18.06) for the bodily pain scale of the spouses' SF-36 in the other group, following the Speaking Out programme.

12.5.1.2 Economic evidence

Literature review

No relevant economic evaluations comparing listener advice skills/information to family members /carers to improve communication in people with aphasia after stroke with usual care or no intervention were identified.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

Costs of the intervention were estimated based on a study by Van der Gaag *et al*, 2008[268]. This study was a cost analysis of various speech and language programmes. Costs were calculated on the basis of 7 sessions with 17 patients per session. Based on the resource use breakdown shown in **Table 83**, the total cost per patient is £517. It is assumed this is on top of usual care.

Table 83: Intervention costs – listener advice skills/information to family members/carers

Resource	Quantity/hrs.[(a)]	Cost[(b)]
Senior speech and language therapist (band 7)	4	£57/hr. of client contact
Speech and language therapist (band 6)	5	£47/hr. of client contact
Assistant[(c)]	4	£25/hr. spent with a patient
Transport		£40/visit[(a)]
Total cost per patient		£517

(a) Source: Van der Gaag et al, 2008[268]
(b) Estimated based on data and methods from Personal Social Services Research Unit 'Unit costs of health and social care' report and relevant Agenda for Change salary bands[51] (typical salary band identified by clinical GDG members)
(c) Assumed to be costed similar to a band 2 clinical support worker nursing (community)

12.5.1.3 Evidence statements

Clinical evidence statements

One quasi-randomised study[127] of 40 participants found that the trained volunteers scored a statistically significant higher rating of skill in acknowledging and revealing competence of their partners with aphasia using the MSCA (measure of supported conversation for adults with aphasia), compared with the untrained volunteers (MODERATE CONFIDENCE IN EFFECT).

One quasi-randomised study[127] of 40 participants found that there was no significant difference in the rating of MPCA – interaction: social connection (rated by aphasic individuals) between those who received the Supported Conversation for Adults with Aphasia (SCA) intervention with trained volunteers compared with usual care at the end of the intervention (LOW CONFIDENCE IN EFFECT).

One quasi-randomised study[127] of 40 participants found that those who received the Supported Conversation with Adults intervention with trained volunteers scored a statistically significant higher rating of MPCA – transaction: message exchange (rated by aphasic individuals) compared with usual care at the end of the intervention (MODERATE CONFIDENCE IN EFFECT).

Economic evidence statements

No cost effectiveness evidence was identified.

12.5.2 Recommendations and link to evidence

	76. Offer training in communication skills (such as slowing down, not interrupting, using communication props, gestures, drawing) to the conversation partners of people with aphasia after stroke.
Relative value placed on the outcomes considered	Any outcome reported in the studies was included in the review. It was noted that the Kagan study[127] measured both the acquired skills of patients and the volunteer listeners. The GDG felt that in the context of conversation partners, it was important to consider outcomes for both groups of participants. No quality of life outcomes were addressed in the evidence presented. The GDG considered that these outcome measures would consider the social and psychological challenges associated with aphasia which are particularly relevant to this intervention. The lack of standardised outcomes in the studies was noted.
Quality of evidence	The GDG agreed that evidence presented was limited to two, small studies which might be regarded as feasibility studies and therefore not robust. [127] [288] However the GDG noted that the Kagan study demonstrated training volunteers resulted in a positive benefit for the measure of skill outcomes and also demonstrated a benefit in participation in conversation by the person with aphasia. Confidence in the results shown for these outcomes was graded as moderate due to unclear randomisation. Another small study [288] reported a significant improvement in those who received a 10 week functional communication therapy delivered by trained volunteers. However these results were not presented in numerical data that could be included in the GRADE analysis. The difficulty of recruiting a suitably large patient population and volunteers for this type of intervention was recognised. It was agreed that the feasibility of offering this intervention and its applicability to UK practice was demonstrated.
Trade-off between clinical benefits and harms	The GDG discussed the definition of listeners' advice and the elements of supported conversation training. The GDG considered there were likely to be benefits from providing simple communication skills training to family members, carers and volunteers and the types of skills employed within the studies reviewed should be given as examples such as slowing speech down, not interrupting, using gestures and writing or drawing. The GDG acknowledged that the Kagan study[127] may have different applicability when interventions are delivered to family members where other factors may impact.
Economic considerations	No cost effective evidence was found. The cost of providing training in communication skills to the conversation partners of people with aphasia was estimated at around £517 per patient. The GDG considered this cost likely to be offset by the benefits of training the conversation partners.

13 Movement

Weakness is common after stroke; this may arise due to the upper motor neuron lesion compounded by inactivity as a consequence of limited physical mobility. Weakness limits patients' ability to move the body, including changing body position, transferring from one place to another, and walking as well as upper limb functions such as carrying, moving or manipulating objects. It also limits performance of activities of daily living and may lead to a more generalised loss of fitness.

The ability to walk following a stroke is often affected or lost due to multiple and complex deficits of motor and sensory systems giving rise to loss of movement, balance and postural control. Rehabilitation of gait ideally attempts to restore a normal walking pattern or if this is not possible to develop a compensatory approach using various aids to promote a safe and functional level of mobility. The ability to walk following a stroke is often seen by both the patient with stroke and their team as a major desirable outcome at any stage throughout the rehabilitation journey and significant time and effort is often required by the patient and their team in order to re-educate gait and promote independent mobility.

Maximising upper limb recovery after stroke similarly requires significant time and effort by the patient after stroke and the rehabilitation team. It has been estimated that upper limb paralysis affects one third of the stroke population. The site and size of the lesion is a major determinant of outcome, with some people after stroke having such severe loss that no amount of therapy will affect functional recovery. However, a significant proportion of people following stroke will regain good arm function through spontaneous recovery. In the remainder, additional therapy may improve outcomes.

Many of the techniques used to support the patient in relearning motor skills depend on repetitive task practice. Repetitive task training encompasses a number of ideas; firstly that repetitive practice early after stroke may lead to beneficial neuroplastic changes within the brain; secondly that repetitive practice reduces weakness; thirdly, that complex movements can be broken down into their components allowing practice of simple elements before incorporating the entire movement; fourthly, that varying task complexity and training schedules (distributed practice, contextual interference) promotes motor learning and generalisation to real life situations and retention of skills; and fifthly that feedback is critical to learning the motor skills.

In addition strength training can be used to address the secondary muscle weakness that arises as a result of inactivity. The underlying mechanisms of neuromuscular weakness after stroke possibly include atrophy of type II fibers, increased proportion of type I fibers, loss of motor units, collateral reinnervation, and altered firing of motor unit groups. It is thought that remodelling of motor units occurs in the months after stroke and it may be possible to enhance this process with therapies directed toward increasing muscle strength and thus functional ability.

In practice the distinction between strength training and repetitive task practice may be less clear, for example, treadmill training with body weight support may be used to facilitate a better gait pattern while building strength and endurance.

13.1 Strength training

Decreased muscle power is common after stroke; this may be due to compromised muscle function post-stroke, compounded by inactivity as a consequence of limited physical mobility. Decreased muscle power limits patients' abilities in activities of daily living and may lead to a more generalised loss of fitness.

Strength training through repetitive practice may represent one approach to improving upper and lower function after stroke.

13.1.1 Evidence review: In people after stroke what is the clinical and cost effectiveness of strength training versus usual care on improving function and reducing disability?

Clinical Methodological Introduction	
Population	Adults and young people 16 or older who have had a stroke
Intervention	• Upper limb strength training and / or • Lower limb strength training Trunk Types of interventions include: weight training, resistance training, Isometric and Isotonic exercises, circuit training for strength
Comparison	Usual care
Outcomes	Upper Limb • MRC Scale • Newton Metres • Fugl-meyer Assessment • Action Research Arm Test (ARAT) • Functional Independence Measurement (FIM) • Barthel Index • Adverse events –pain or spasticity Lower Limb/Trunk • Timed Up and Go Test • Any timed walk • Walking distance • Functional Independence Measure (FIM) • Barthel Index • Adverse events – falls, pain or spasticity • Newton Metres

13.1.1.1 Clinical Evidence Review

Searches were conducted for systematic reviews and RCTs comparing the clinical effectiveness of strength training with usual care to improve function and reduce disability for adults and young people 16 or older who have had a stroke. Only studies with a minimum sample size of 20 participants (10 in each arm) were selected. Nine RCTs were identified.

Table 84 summarises the population, intervention, comparison and outcomes for each of the studies.

Table 84: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix H.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Cooke, 2010[47]	Inpatients with stroke (1-13 weeks post stroke onset) who were independently mobile (with or without aids) prior to the index stroke and were able to follow a 1 stage command.	Functional strength training plus conventional physiotherapy; focused on repetitive, progressive resistive exercise during goal oriented functional	Routine conventional physiotherapy by a clinical physiotherapist included soft tissue mobilisation, facilitation of	• Walking speed (m/sec) • Knee flexion peak torque • Knee extension peak torque

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
		activity. All additional therapy was delivered using standardized treatment schedules for up to 1 hour, 4 days/week for 6 weeks. (N=36)	muscle activity, facilitation of coordinated multi joint movement, tactile and proprioceptive input, resistive exercise and functional retraining. (N=38)	
Donaldson, 2009[68]	Stroke patients (mean time after stroke: 20.2 days (SD=14.0)).	Functional strength training (FST) plus conventional physiotherapy by a physiotherapist up to 1 hour, 4 days/week for 6 weeks (total 24 hours). FST was based on the positioning of the hand and then using it to manipulate objects. Treatment was progressed using repetition, altering the size and weight of items, and using heavier weights. (N=10)	Conventional physiotherapy instructed by a physiotherapist. (N=10)	• Action Research Arm Test (ARAT) • Hand Grip force (N) • Pinch grip force(N) • Isometric elbow flexion force (N) • Isometric elbow extension force (N).
Flansbjer, 2008[84]	Stroke patients (mean time since stroke: 18.9 months (SD 7.9) for the training group and 20 months (SD 11.6) for the control group.	Progressive resistance training provided for 10 weeks twice weekly using Leg Extension/Curl Rehabilitation exercise machine. Each (N=15)	Usual care: patients were encouraged to continue usual daily activities and training but not to engage in any progressive resistance training (PRT). (N=9)	• Gait performance - Timed 'Up and Go' test - Fast walking speed - 6 minute walk test (m).
Kim, 2001 [136]	Chronic stroke survivors, with residual unilateral weakness; aged 50 years or older; history of a single stroke at least 6 months before participating in the study.	Maximal isokinetic strengthening with an isokinetic dynamometer consisting of three 45-minute sessions per week for 6 consecutive weeks for a total of 18 sessions. Participants were asked to walk at their most comfortable speed (i.e., self-	The same as intervention except the resisted contractions replaced with passive range of motion movements. (N=10)	• Self-selected gait speed/Habitual gait speed (m/s) • Maximal gait speed (m/s)

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
		selected speed) for 5 trials and then "safely as fast as possible" (i.e., maximal speed) for another 5 trials along an 8-m walkway. (N=10)		
Langhammer, 2007[142]	Stroke patient with hemisphere lesion: Right (n): 19 intensive exercise ; 19 regular exercise Left (n): 16 intensive exercise; 21 regular exercise.	Functional exercise programme; high intensity of endurance, strength, and balance. Individualised training programmes aimed at functional improvements but with variations, for example getting up from a chair, walking indoors, Nordic walking outdoors, stationary bicycling and stair walking, where the physiotherapist monitored the levels of intensity. Total treatment period at least 80 hours (minimum 20 hours every third month for the first year after discharge; 2-3 times per week if at home or attending private physiotherapy practice or daily if in rehabilitation ward) (N=35)	Usual care: physical exercises in accordance with the routines in the community, and only if needed they would have a follow-up (N=40)	• Barthel Index (BI) • Grip strength (paretic, non-paretic hand)
Moreland, 2003[178]	Stroke patients : Non-lacunar- 36 (53%) progressive resistance; 36 (55%) control group.	Strength training: conventional physiotherapy plus progressive resistance exercises with weights at waist or on lower extremities. Use of ankle exerciser to which variable weights applied for 30 minute exercise sessions (2 sets of 10	Conventional physiotherapy but no external resistance was applied with weights. (N=65)	• 2-minute walk test (m)

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
		repetitions) 3 times a week. (N=68)		
Ouellette, 2004 [195]	Patients aged ≥50 years; 6 months to 6 years following a single unilateral mild to moderate stroke with residual lower extremity hemi paresis, community dwelling; independent ambulation with or without an assistive device	Progressive Resistance Training: Subjects performed seated bilateral leg press (LP); unilateral paretic and non-paretic limb knee extension (KE), unilateral ankle dorsiflexion (DF), and planterflexion (PF) 3 times per week for 12 weeks. Habitual and maximal Gait Velocities – Subjects were instructed to walk 10 metres at their normal and maximal velocity respectively. (N=21)	Bilateral range of motion (ROM) and upper body flexibility exercises performed 3 times per week. (N=21)	• Six-minute walk (min) • Habitual Gait Velocity /self-gait speed (m/sec) • Maximal Gait Velocity (m/sec)
Winstein, 2004[285]	Stroke patients (mean time since stroke 16 days (SD 17.7). 85 % of patients had ischaemic type of stroke.	Strength and motor control training (ST): resistance to available arm motion. (N=21)	Standard care by an occupational therapist: muscle facilitation exercises, neuromuscular electric stimulation applied primarily for shoulder subluxation, stretching exercises, activities of daily living (self-care where the upper limb was used as an assist) and caregiver training. (N=21)	• Fugl-Meyer assessment (FMA): -range of movement -pain -sensory -motor function • FIM: -mobility -self-care
Galvin 2011[88]	40 participants were assessed at 2 weeks after stroke and were those with a confirmed diagnosis of a first unilateral stroke (MRI or CT), no impairment	Usual care physiotherapy plus family mediated exercise intervention. Individualised FAME programs were conducted for 35	Usual care physiotherapy (N=20)	• Lower limb section of the Fugl-Meyer Assessment (LL-FMA). • Motor assessment Scale (MAS), • Berg Balance Scale

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
	of cognition (≥24 of 30 on the Mini Mental State Examination), participating in a physiotherapy program and a family member willing to participate in the program. To control for heterogeneity individuals who scored from 3.2 to 5.2 on the Orpington Prognostic Scale were recruited. The family member had to be medically stable and physically able to assist in the delivery of exercises.	minutes daily at the bedside with the assistance of their nominated family member. The emphasis of the lower limb exercise intervention was on achieving stability and improving gait velocity and lower limb strength based on patterns and were progress according to the individual's ability (N=20)		(BBS), • 6-MWT • Barthel Index (BI)

Comparison: Functional strength training (upper, lower limb) versus usual care

Table 85: Upper limb functional strength training usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
						Upper limb Functional strength training	Usual care	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Mean (SD)	Mean (SD)	Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
Barthel Index (6 months follow-up) (Better indicated by higher values)										
1 Langhammer [142]2007	RCT- double blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	84.5 (23.9)	91.2 (19.9)	- 6.7 (-17.55 to 4.15)	MD 6.7 lower (17.55 lower to 4.15 higher)	Low
Grip strength paretic hand (6 months follow-up) (Better indicated by higher values)										
1 Langhammer 2007[142]	RCT- double blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	No serious imprecision	0.55 (0.42)	0.55 (0.41)	0 (-0.2 to 0.2)	MD 0 higher (0.2 lower to 0.2 higher)	Moderate
Grip strength non-paretic hand (6 months follow-up) (Better indicated by higher values)										
1 Langhammer 2007[142]	RCT- double blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	0.77 (0.35)	0.81 (0.31)	-0.04 (-0.2 to 0.12)	MD 0.04 lower (0.2 lower to 0.12 higher)	Low

Quality assessment						Summary of findings				
						Upper limb Functional strength training	Usual care	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Mean (SD)	Mean (SD)	Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
Barthel Index (1 year follow-up) (Better indicated by higher values)										
1 Langhammer 2007[142]	RCT- double blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Very serious imprecision(e)	80.8 (29.5)	87.7 (27.8)	- 6.9 (-21.05 to 7.25)	MD 6.9 lower (21.05 lower to 7.25 higher)	Very low
Grip strength paretic hand (1 year follow-up) (Better indicated by higher values)										
1 Langhammer 2007[142]	RCT- double blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	0.63 (0.46)	0.67 (0.43)	-0.04 (-0.26 to 0.18)	MD 0.04 lower (0.26 lower to 0.18 higher)	Low
Grip strength non-paretic hand (1 year follow-up) (Better indicated by higher values)										
1Langhammer 2007[142]	RCT- double blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	0.87 (0.4)	0.99 (0.32)	- 0.12 (-0.3 to 0.06)	MD 0.12 lower (0.3 lower to 0.06 higher)	Low
Action Research Arm Test (ARAT) (3 months follow-up) (Better indicated by higher values)										
1 Donaldson 2009[68]	RCT-single blinded	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision(d)	43.6 (18.9)	45 (13.93)	-1.4 (-16.58 to 13.78)	MD 1.4 lower (16.58	Low

Quality assessment						Summary of findings				
						Upper limb Functional strength training	Usual care	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Mean (SD)	Mean (SD)	Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
									lower to 13.78 higher)	
Grip force (N) (3 months follow-up) (Better indicated by higher values)										
1 Donaldson 2009[68]	RCT-single blinded	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision(c)	58.5 (60.18)	64.75 (39.25)	- 6.25 (-52.41 to 39.91)	MD 6.25 lower (52.41 lower to 39.91 higher)	Low
Pinch force (N) (3 months follow-up) (Better indicated by higher values)										
1 Donaldson 2009[68]	RCT-single blinded	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision(c)	25.8 (21.26)	24.5 (19.7)	1.3 (-17.67 to 20.27)	MD 1.3 higher (17.67 lower to 20.27 higher)	Low
Elbow flexion force (N) (3 months follow-up) (Better indicated by higher values)										
1 Donaldson 2009[68]	RCT-single blinded	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision(c)	59.5 (44.69)	75 (38.67)	-15.5 (-54.04 to 23.04)	MD 15.5 lower (54.04 lower to 23.04 higher)	Low
Elbow extension fore (N) (3 months follow-up) (Better indicated by higher values)										

Quality assessment						Summary of findings				
						Upper limb Functional strength training	Usual care	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Mean (SD)	Mean (SD)	Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
1 Donaldson 2009[68]	RCT-single blinded	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision(c)	49.2 (34.19)	68.63 (39.61)	-19.43 (-54.11 to 15.25)	MD 19.43 lower (54.11 lower to 15.25 higher)	Low

[a] Allocation concealment not reported. 16% lost to follow-up.
[b] Mean difference did not reach the agreed MID of 9.25 points.
[c] Confidence interval crossed one end of default MID.
[d] Mean difference did not reach the agreed MID of 12 and 17 points for the affected dominant and non-dominant sides respectively
[e] Confidence interval crossed both ends of default MID.

Comparison: lower limb functional strength training versus usual care

Table 86: Lower limb functional strength training versus usual care – Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
						Lower limb Functional strength training	Usual care	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Mean (SD)	Mean (SD)	Relative Mean difference (MD) (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
Walking speed (m/sec) (3 months follow-up) (Better indicated by higher values)										
1 Cooke 2010[47]	RCT-single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	No serious imprecision	0.46 (0.37)	0.44 (0.39)	0.02 (-0.19 to 0.23)	MD 0.02 higher (0.19 lower to 0.23 higher)	Moderate
Knee flexion peak torque (3 months follow-up) (Better indicated by higher values)										
1 Cooke 2010[47]	RCT-single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	29.4 (21.2)	25.2 (22.9)	4.2 (-9.36 to 17.76)	MD 4.2 higher (9.36 lower to 17.76 higher)	Low
Knee extension peak torque (3 months follow-up) (Better indicated by higher values)										
1 Cooke 2010[47]	RCT-single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	42.1 (27.5)	37.9 (27.8)	4.2 (-12.71 to 21.11)	MD 4.2 higher (12.71 lower to 21.11 higher)	Low

(a) 26% lost to follow-up at 12 weeks.
(b) Confidence interval crossed one end of default MID

Comparison: Resistance training versus usual care

Table 87: Resistance training versus usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Resistance training Mean (SD)	Usual care Mean (SD)	Mean difference (MD) (95% CI)	Mean Difference (95% CI)	Confidence (in effect)
FIM – mobility changes (post-treatment effect) (Better indicated by higher values)										
1 Winstein 2004[285]	RCT– unblinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	15 (7.14)	14.1 (7.58)	0.90 (-3.66, 5.46)	MD 0.90 higher (3.66 lower to 5.46 higher)	Low
FIM – mobility changes (9 months follow-up) (Better indicated by higher values)										
1 Winstein 2004[285]	RCT–unblinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	2.44 (1.82)	5.67 (5.47)	-3.23 (-6.14 to -0.32)	MD 3.23 lower (6.14 to 0.32 lower)	Low
FIM- self-care changes (post-treatment effect) (Better indicated by higher values)										
1 Winstein 2004[285]	RCT– unblinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	16.15 (5.81)	17 (5.17)	-0.85 (-4.26, 2.56)	MD 0.85 lower (4.26 lower to 2.56 higher)	Low
FIM- self-care changes (9 months follow-up) (Better indicated by higher values)										

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Resistance training Mean (SD)	Usual care Mean (SD)	Mean difference (MD) (95% CI)	Mean Difference (95% CI)	Confidence (in effect)
1 Winstein 2004[285]	RCT–unblinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	2.75 (4.34)	6.07 (4.62)	-3.32 (-6.48 to -0.16)	MD 3.32 lower (6.48 to 0.16 lower)	Low
Upper extremity Fugl-Meyer Assessment – Range of Movement changes (post-treatment effect) (Better indicated by higher values)										
1 Winstein 2004[285]	RCT– unblinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	-0.75 (2)	-0.6 (1.93)	-0.15 (-1.37, 1.07)	MD 0.15 lower (1.37 lower to 1.07 higher)	Low
Upper extremity Fugl-Meyer Assessment– Range of Movement changes (9 months follow-up) (Better indicated by higher values)										
1 Winstein 2004[285]	RCT– unblinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	-2.13 (2.96)	-0.33 (1.45)	- 1.8 (-3.43 to -0.17)	MD1.8 lower (3.43 to 0.17 lower)	Low
Upper extremity Fugl-Meyer Assessment - Pain changes (post-treatment effect) (Better indicated by higher values)										
1 Winstein 2004[285]	RCT– unblinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	-0.7 (2.3)	-0.6 (1.79)	-0.10 (-1.38, 1.18)	MD 0.10 lower (1.38 lower to 1.18 higher)	Low
Upper extremity Fugl-Meyer Assessment - Pain changes (9 months follow-up) (Better indicated by higher values)										

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Resistance training Mean (SD)	Usual care Mean (SD)	Mean difference (MD) (95% CI)	Mean Difference (95% CI)	Confidence (in effect)
1 Winstein 2004[285]	RCT– unblinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	-1.19 (4)	-1 (2.88)	-0.19 (-2.63 to 2.25)	MD 0.19 lower (2.63 lower to 2.25 higher)	Low
Upper extremity Fugl-Meyer Assessment -sensory changes (post-treatment effect) (Better indicated by higher values)										
1 Winstein 2004[285]	RCT– unblinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	1.3 (2.23)	0.75 (1.33)	0.55 (-0.59, 1.69)	0.55 higher (0.59 lower to 1.69 higher)	Low
Upper extremity Fugl-Meyer Assessment -sensory changes (9 months follow-up) (Better indicated by higher values)										
1 Winstein 2004[285]	RCT– unblinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	0.25 (0.68)	0.07 (1.03)	0.18 (-0.44 to 0.8)	MD 0.18 higher (0.44 lower to 0.8 higher)	Low
Upper extremity Fugl-Meyer Assessment - motor function changes (post-treatment effect) (Better indicated by higher values)										
1 Winstein 2004[285]	RCT– unblinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	18.2 (13.54)	9.05 (7.6)	9.15 (2.35, 15.95)	MD 9.15 higher (2.35 to 15.95 higher)	Low
Upper extremity Fugl-Meyer Assessment - motor function changes (9 months follow-up) (Better indicated by higher values)										

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Resistance training Mean (SD)	Usual care Mean (SD)	Mean difference (MD) (95% CI)	Mean Difference (95% CI)	Confidence (in effect)
1 Winstein 2004[285]	RCT – unblinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	5.38 (9.11)	8.33 (11.26)	-2.95 (-10.19 to 4.29)	MD 2.95 lower (10.19 lower to 4.29 higher)	Low
Timed up and go test (sec) (5 months follow-up) (better indicated by lower values)										
1Flansbjer 2008[84]	RCT –single blinded	Serious limitations (e)	No serious inconsistency	No serious indirectness	Very serious imprecision(d)	23.6 (11.1)	26.7 (18.9)	-3.1 (-16.67 to 10.47)	MD 3.1 lower (16.67 lower to 10.47 higher)	Very low
Fast walking speed (m/sec) (5 months follow-up) (Better indicated by higher values)										
1 Flansbjer 2008[84]	RCT- single blinded	Serious limitations (e)	No serious inconsistency	No serious indirectness	Serious imprecision(h)	16.1 (9.9)	19.4 (17.8)	-3.3 (-15.96 to 9.36)	MD 3.3 lower (15.96 lower to 9.36 higher)	Low
2 minute walk test (m) (6 months follow-up) (Better indicated by higher values)										
1 Moreland 2003[178]	RCT- single blinded	Serious limitations(g)	No serious inconsistency	No serious indirectness	No serious imprecision	58.6 (52.7)	63.2 (49.1)	-4.6 (-23.98 to 14.78)	MD 4.6 lower (23.98 lower to 14.78 higher)	Moderate

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Resistance training Mean (SD)	Usual care Mean (SD)	Mean difference (MD) (95% CI)	Mean Difference (95% CI)	Confidence (in effect)
6 minute walk test (m) (3 months follow-up) (Better indicated by higher values)										
1 Ouellette, 2004 [195]	RCT- Single blinded	Serious limitation(e)	No serious inconsistency	No serious indirectness	No serious imprecision	239.1 (30.3)	234.8 (36.9)	4.30 (-16.12, 24.72)	MD 4.3 higher (16.12 lower to 24.72 higher)	Moderate
6 minute walk test (m) (5 months follow-up) (Better indicated by higher values)										
1 Flansbjer 2008[84]	RCT- single blinded	Serious limitations(e)	No serious inconsistency	No serious indirectness	Very serious imprecision(f)	251 (144)	240 (140)	11.00 (-105.95, 127.95)	MD 11 higher (105.95 lower to 127.95 higher)	Very low
Self-selected/Habitual gait speed (Better indicated by higher values)										
2 Kim, 2001 [136], Ouellette, 2004 [195]	RCT- double blinded (Kim) RCT- single blinded (Ouellette)	Serious limitations(i)	No serious inconsistency	No serious indirectness	Serious imprecision(j)	Kim: 0.04 (0.13) Ouellette: 0.64 (0.08)	Kim: 0.09 (0.07) Ouellette: 0.64 (0.09)	-0.01 (-0.06, 0.03)	MD 0.01 lower (0.06 lower to 0.03 higher	Low
Maximal gait speed (Better indicated by higher values)										
2	RCT- double	Serious	No serious	No serious	Serious	Kim: 0.05	Kim: 0.07	-0.01 (-	MD 0.01	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Resistance training Mean (SD)	Usual care Mean (SD)	Mean difference (MD) (95% CI)	Mean Difference (95% CI)	Confidence (in effect)
Kim, 2001 [136], Ouellette, 2004 [195]	blinded (Kim) RCT- single blinded (Ouellette)	limitations(i)	inconsistency	indirectness	imprecision(j)	(0.09) Ouellette: 0.86 (0.11)	(0.08) Ouellette: 0.87 (0.12)	0.07, 0.04)	lower (0.07 lower to 0.04 higher	

[a] Unblinded study. Unclear randomization and inadequate allocation concealment. 27% lost to follow-up at 9 months.
[b] Mean difference did not reach the agreed MID of 17 points for the motor scale and the 3 points for the cognitive scale.
[c] Mean difference did not reach the agreed MID of 10% between the intervention and control groups.
[d] Mean difference did not reach the agreed MID of 10 sec between the intervention and control groups.
[e] Allocation concealment not reported; No details of randomisation
[f] Confidence interval crossed both ends of default MID.
[g] Unclear blinding; 20% lost to follow-up at 6 months.
[h] Confidence interval crossed one end of the default MID.
(i) Unclear randomisation; unclear allocation concealment
(J) Mean difference did not reach the agreed MID of 0.2m/sec between the intervention and control groups.

Comparison: Family mediated exercise intervention versus usual care (physiotherapy)

Table 88: GRADE characteristics and clinical summary of findings

Quality assessment						Summary of Findings				
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Family mediated strength training Mean (SD)	Usual care (physiotherapy) Mean (SD)	Effect		Confidence (in effect)
								Mean Difference (95% CI)	Mean Difference (95% CI)	
Lower limb Fugl-Meyer Assessment - Post intervention (follow-up 8 weeks; measured with: Mean change from baseline; range of scores: 0-36; Better indicated by higher values)										
1 Galvin 2011[88]	randomised trials – single (assessor) blinded	serious (a)	no serious inconsistency	no serious indirectness	serious(b)	9.5 (9.9)	1.75 (6.3)	7.75 (2.61, 12.89)	MD 7.75 higher (2.61 to 12.89 higher)	LOW
Lower limb Fugl-Meyer Assessment - Follow-up after 3 months (measured with: Mean change from post intervention; range of scores: 0-36; Better indicated by higher values)										
Galvin 2011[88]	randomised trials – single (assessor) blinded	serious (a)	no serious inconsistency	no serious indirectness	no serious imprecision	1.6 (2.4)	1.3 (5.2)	0.3 (-2.21, 2.81)	MD 0.3 higher (2.21 lower to 2.81 higher)	MODERATE
Motor assessment scale - Post intervention (follow-up 8 weeks; measured with: Mean change from baseline; range of scores: 0-48; Better indicated by higher values)										
Galvin 2011[88]	randomised trials – single (assessor) blinded	serious (a)	no serious inconsistency	no serious indirectness	serious(c)	11.9 (7.8)	4.75 (6.2)	7.15 (2.78, 11.52)	MD 7.15 higher (2.78 to 11.52 higher)	LOW
Motor assessment scale - Follow-up after 3 months (measured with: Mean change from post intervention; range of scores: 0-48; Better indicated by higher values)										
Galvin 2011[88]	randomised trials –	serious (a)	no serious inconsistency	no serious indirectness	serious(c)	1.8 (3.8)	0.7 (2.6	1.1 (-0.92,	MD 1.1 higher (0.92 lower to	LOW

Quality assessment						Summary of Findings				
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Family mediated strength training Mean (SD)	Usual care (physiotherapy) Mean (SD)	Effect		Confidence (in effect)
								Mean Difference (95% CI)	Mean Difference (95% CI)	
	single (assessor) blinded							3.12)	3.12 higher)	
Berg Balance Scale - Post intervention (follow-up 8 weeks; measured with: Mean change from baseline; range of scores: 0-56; Better indicated by higher values)										
Galvin 2011[88]	randomised trials – single (assessor) blinded	serious (a)	no serious inconsistency	no serious indirectness	serious(c)	22.8 (18.1)	9 (9)	13.8 (4.94, 22.66)	MD 13.8 higher (4.94 to 22.66 higher)	LOW
Berg Balance Scale - Follow-up after 3 months (measured with: Mean change from post intervention; range of scores: 0-56; Better indicated by higher values)										
Galvin 2011[88]	randomised trials – single (assessor) blinded	serious (a)	no serious inconsistency	no serious indirectness	serious(d)	0.9 (2.5)	1.8 (8.5)	0.9 (-4.78, 2.99)	MD 0.9 lower (4.78 lower to 2.98 higher)	LOW
6-Minute Walk Test - Post intervention (follow-up 8 weeks; measured with: Mean change from baseline - metres; Better indicated by higher values)										
Galvin 2011[88]	randomised trials – single (assessor) blinded	serious 1	no serious inconsistency	no serious indirectness	no serious imprecision	164.1 (128.7)	47.2 (50.6)	116.9 (56.29, 177.51)	MD 116.9 higher (56.29 to 177.51 higher)	MODERATE
6-Minute Walk Test - Follow-up after 3 months (measured with: Mean change from post-intervention - metres; Better indicated by higher values)										
Galvin 2011[88]	randomised trials – single (assessor) blinded	serious (a)	no serious inconsistency	no serious indirectness	serious(e)	39.8 (55.4)	-3.5 (32.7)	43.3 (15.11, 71.49)	MD 43.3 higher (15.11 to 71.49 higher)	LOW

Quality assessment						Summary of Findings				
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Family mediated strength training Mean (SD)	Usual care (physiotherapy) Mean (SD)	Effect		Confidence (in effect)
								Mean Difference (95% CI)	Mean Difference (95% CI)	
Barthel Index - Post intervention (follow-up 8 weeks; measured with: Mean change from baseline; range of scores: 0-100; Better indicated by higher values)										
Galvin 2011[88]	randomised trials – single (assessor) blinded	serious (a)	no serious inconsistency	no serious indirectness	no serious imprecision	32.3 (24)	16.3 (14.2)	16 (3.78, 28.22)	MD 16 higher (3.78 to 28.22 higher)	MODERATE
Barthel Index - Follow-up after 3 months (measured with: Mean change from post intervention; range of scores: 0-100; Better indicated by higher values)										
Galvin 2011[88]	randomised trials – single (assessor) blinded	serious (a)	no serious inconsistency	no serious indirectness	very serious(f)	3.8 (8.3)	1.5 (11.6)	2.3 (-3.95, 8.55)	MD 2.3 higher (3.95 lower to 8.55 higher)	VERY LOW

[a] Unclear allocation concealment.
[b] The confidence interval crosses the agreed MID of 10% of the Fugl-Meyer scale from appreciable benefit to no effect in favour of FAME intervention
[c] The confidence interval crosses the default MID (0.5 of standard mean difference) for individual studies, i.e. ranging from appreciable benefit of the FAME intervention to no effect.
[d] The confidence interval crosses the default MID (0.5 of standard mean difference) for individual studies, here ranging from appreciable negative effect of the FAME study to no effect.
[e]The confidence interval crossed the agreed MID of 28 metres, i.e. ranging from appreciable benefit of the FAME study to no effect
[f] The confidence interval crosses both sides of the agreed MID (1.85) ranging from appreciable negative effect to appreciable positive effect associated with the FAME intervention

13.1.1.2 Economic evidence

Literature review

No relevant economic evaluations comparing strength training with usual care were identified.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

The cost of providing strength training (**Table 89**) was estimated based on the resources used in two studies (Flansbjer, 2008[84] and Cooke, 2010[47]) included in the clinical review. The remaining studies included in the clinical review[68,142,178,285] were not used as they did not provide sufficient information about the type or amount of resources used.

Table 89: Intervention costs – muscle power training

Source	Resource use	Unit costs[(a)]	Incremental cost (intervention over usual care)
Resistance training			
Flansbjer 2008[84]	90 minute sessions by physiotherapist including progressive resistance training[(b)] (<6 minutes) for 10 weeks, twice weekly (1.5hrs x 20 = 30hrs)	£45 per hour of client contact (band 6)	£1350
Lower limb strength training			
Cooke 2010[47]	1 hour session by physiotherapist, for 4 days per week for 6 weeks (1hr x 24 = 24hrs)	£45 per hour of client contact (band 6)	£1080

(a) Estimated based on data and methods from the Personal Social Services Research Unit 'Unit costs of health and social care' report and Agenda for Change salary band 6[51] (typical salary band identified by clinical GDG members).

(b) Training was done using a leg extension/curl rehabilitation exercise machine.

These estimates represent the cost of muscle power training provided by NHS or PSS staff in the early phase after stroke. However, in later stages, strength training may be handed over to an appropriately qualified gym instructor and this would have lower costs.

13.1.1.3 Evidence statements

Clinical evidence statements

One study[142] of 75 participants found no significant difference in Barthel Index between those participants who received upper limb functional training and those who received usual care at a follow-up of 6 months (LOW CONFIDENCE IN EFFECT).

One study[142] of 75 participants found no significant difference in grip strength (paretic hand) between those participants who received upper limb functional training and those who received usual care at a follow-up of 6 months (MODERATE CONFIDENCE IN EFFECT

One study[142] of 75 participants found that there was no significant difference in grip strength (non-paretic hand) between those participants who received upper limb functional training and those who received usual care at a follow-up of 6 months (LOW CONFIDENCE IN EFFECT).

One study[142] of 75 participants found no significant difference in Barthel Index between those participants who received upper limb functional training and those who received usual care at a follow-up of 1 year (VERY LOW CONFIDENCE IN EFFECT).

One study[142] of 75 participants found no significant difference in grip strength (paretic hand) between those participants who received upper limb functional training and those who received usual care at a follow-up of 1 year (LOW CONFIDENCE IN EFFECT).

One study[142] of 75 participants found no significant difference in grip strength (non-paretic hand) between those participants who received upper limb functional training and those who received usual care at a follow-up of 1 year (LOW CONFIDENCE IN EFFECT).

One study[68] of 20 participants found no significant difference in Action Research Arm Test (ARAT) between those participants who received upper limb functional training and those who received usual care at 3 months follow-up (LOW CONFIDENCE IN EFFECT)

One study[68] of 20 participants found that there was no significant difference in Grip force (N) between those participants who received upper limb functional training and those who received usual care at 3 months follow-up (LOW CONFIDENCE IN EFFECT).

One study[68] of 20 participants found that there was no significant difference in pinch force (N) between those participants who received upper limb functional training and those who received usual care at 3 months follow-up (LOW CONFIDENCE IN EFFECT).

One study[68] of 20 participants found no significant difference in Elbow flexion force (N) between those participants who received upper limb functional training and those who received usual care at 3 months follow-up (LOW CONFIDENCE IN EFFECT).

One study[68] of 20 participants found no significant difference in Elbow extension force (N) between those participants who received upper limb functional training and those who received usual care at 3 months follow-up (LOW CONFIDENCE IN EFFECT).

One study[47] of 74 participants found no significant difference in walking speed (m/sec) between those participants who received lower limb functional training and those who received usual care at a follow-up of 3 months (MODERATE CONFIDENCE IN EFFECT).

One study[47] of 74 participants found no significant difference in knee flexion peak torque between those participants who received lower limb functional training and those who received usual care at a follow-up of 3 months (LOW CONFIDENCE IN EFFECT).

One study[47] of74 participants found no significant difference in knee extension peak torque between those participants who received lower limb functional training and those who received usual care at a follow-up of 3 months (LOW CONFIDENCE IN EFFECT).

One study[285] of43 participants found that there was no significant difference in FIM – mobility score between the participants who received resistance training and those who received usual care after treatment (LOW CONFIDENCE IN EFFECT).

One study[285] of43 participants found that usual care was associated with statistically significant improvement in FIM – mobility score compared to resistance training at a follow-up of 9 months, although this difference was not of clinical significance (LOW CONFIDENCE IN EFFECT).

One study[285] of43 participants found that there was no significant difference in FIM –self-care score between the participants who received resistance training and those who received usual care after treatment (LOW CONFIDENCE IN EFFECT).

One study[285] of 43 participants found that usual care was associated with statistically significant improvement in FIM – self-care score compared to resistance training at 9 months follow-up, although this difference was not of clinical significance (LOW CONFIDENCE IN EFFECT).

One study[285] of43 participants found that there was no significant difference in Fugl-Meyer –ROM score between the participants who received resistance training and those who received usual care after treatment (LOW CONFIDENCE IN EFFECT).

One study[285] of 64 participants found that usual care was associated with statistically significant improvement in Fugl-Meyer –range of motion score compared to resistance training at a follow-up of 9 months (LOW CONFIDENCE IN EFFECT).

One study[285] of43 participants found that there was no significant difference in Fugl-Meyer –pain score between the participants who received resistance training and those who received usual care after treatment and at a follow-up of 9 months (LOW CONFIDENCE IN EFFECT).

One study[285] of 64 participants found no significant difference in Fugl-Meyer –sensory score between those participants who received resistance training and those who received usual care after treatment and at a follow-up of 9 months (LOW CONFIDENCE IN EFFECT).

One study[285] of 43 participants found that resistance training was associated with statistically significant improvement in FIM – motor function score compared to usual care after treatment, although this difference was not of clinical significance (LOW CONFIDENCE IN EFFECT).

One study[285] of 64 participants found no significant difference in Fugl-Meyer –motor function score between those participants who received resistance training and those who received usual care at a follow-up of 9 months (LOW CONFIDENCE IN EFFECT).

One study[84]of 24 participants found no significant difference in gait performance assessed by timed up and go test (sec) between those participants who received resistance training and those who received usual care at a follow-up of 5 months (VERY LOW CONFIDENCE IN EFFECT).

One study[84] of 24 participants found no significant difference in gait performance assessed by fast gait speed (10m/sec) between those participants who received resistance training and those who received usual care at a follow-up of 5 months (LOW CONFIDENCE IN EFFECT)

One study[178] of 133 participants found no significant difference in 2 minute walk test between those participants who received resistance training and those who received usual care at a follow-up of 6 months (MODERATE CONFIDENCE IN EFFECT).

One study[195] of 42 participants found no significant difference in gait performance assessed by 6 minute walk test between those participants who received resistance training and those who received usual care at a follow-up of 3 months (MODERATE CONFIDENCE IN EFFECT).

One study[84], of 24 participants found no significant difference in gait performance assessed by 6 minute walk test between those participants who received resistance training and those who received usual care at a follow-up of 5 months (VERY LOW CONFIDENCE IN EFFECT).

Two studies[136],[195] of 62 participants found no significant difference in self-selected/habitual gait speed between those participants who received resistance training and those who received usual care (LOW CONFIDENCE IN EFFECT)

Two studies[136],[195] of 62 participants found no significant difference in maximal gait speed between those participants who received resistance training and those who received usual care (LOW CONFIDENCE IN EFFECT)

Family mediated exercise (FAME) intervention compared to usual care (physiotherapy)

One study [88] of 40 participants found a significant improvement in Lower Limb Fugl-Meyer –motor function associated with the FAME intervention compared to usual care at the end of the 8 week intervention (LOW CONFIDENCE IN EFFECT). This improvement was not maintained at the end of the 3 months follow-up period (MODERATE CONFIDENCE IN EFFECT).

One study [88] of 40 participants found a significant improvement in everyday motor function (as assessed by the Motor Assessment Scale) associated with the FAME intervention compared to usual care at the end of the 8 week intervention (LOW CONFIDENCE IN EFFECT). This improvement was not maintained at the end of the 3 months follow-up period (LOW CONFIDENCE IN EFFECT).

One study [88] of 40 participants found a significant improvement in person's static and dynamic balance abilities (as assessed by the Berg Balance Scale) associated with the FAME intervention compared to usual care at the end of the 8 week intervention (LOW CONFIDENCE IN EFFECT). This improvement was not maintained at the end of the 3 months follow-up period (LOW CONFIDENCE IN EFFECT).

One study [88] of 40 participants found a significant improvement in functional exercise capacity (as assessed by the 6 minute walk test) associated with the FAME intervention compared to usual care at the end of the 8 week intervention (MODERATE CONFIDENCE IN EFFECT). This improvement was still significant at the end of the 3 months follow-up period but the effect was not as large as post intervention (LOW CONFIDENCE IN EFFECT).

One study [88] of 40 participants found a significant improvement in the performance in activities of daily living (as assessed by the Barthel Index) associated with the FAME intervention compared to usual care at the end of the 8 week intervention (MODERATE CONFIDENCE IN EFFECT). This improvement was still significant at the end of the 3 months follow-up period but the effect was not as large as post intervention (LOW CONFIDENCE IN EFFECT).

Economic evidence statements

No cost effectiveness evidence was identified.

13.1.2 Recommendations and link to evidence

	77. Provide physiotherapy for people who have weakness in their trunk or upper or lower limb, sensory disturbance or balance difficulties after stroke that have an effect on function. **78. People with movement difficulties after stroke should be treated by physiotherapists who have the relevant skills and training in the diagnosis, assessment and management of movement in people with stroke.** **79. Treatment for people with movement difficulties after stroke should continue until the person is able to maintain or progress function either independently or with assistance from others (for example, rehabilitation assistants, family members, carers or fitness instructors).**

	80. Consider strength training for people with muscle weakness after stroke. This could include progressive strength building through increasing repetitions of body weight activities (for example, sit-to-stand repetitions), weights (for example, progressive resistance exercise), or resistance exercise on machines such as stationary cycles.
Relative values of different outcomes	The range of outcomes reflected impairment (force), activity (walking speed and distance, Action Research Arm test), and dependence (Barthel Index and Functional Independence Measure). Improvements in strength would be postulated to lead to improvements of function and thus measures of mobility, activity, and dependence are of potentially more interest. However, in small studies measures of impairment may be responsive to the intervention. Adverse events were also regarded as an important outcome, particularly the development of increased tone. The GDG noted that some health professionals have expressed a concern that strength training may be associated with an increase in tone that in time, may lead to deterioration in function. In this context, the GDG considered it important to recognise the incidence of disabling spasticity in stroke which has been reported as 4% by Lumstrom et al. [161]
Trade-off between clinical benefits and harms	One study [84] stated there were no injuries associated with the resistance training exercise machine used. None of the other studies reported any adverse events from the strength training interventions. The GDG agreed that that there would not normally be any detrimental effect from these types of interventions. Weakness of the face, upper limb, trunk and lower limb are common deficits after stroke, As well as strength, sensory disturbance and balance difficulties impact on movement. It was felt that trained physiotherapists with the relevant skills and training in the diagnosis, assessment and management of movement in people with stroke should regularly monitor and treat people with movement difficulties until they are able to maintain or progress function either independently or with assistance from others (rehabilitation assistants, carers, fitness instructors etc.). One study reported significant improvements in motor and balance function associated with strength training using family members as co-trainers. The evidence for outcomes from this study were of low to moderate quality. However, improvements were not maintained over a three month follow-up period.
Economic considerations	No cost effectiveness studies were identified for this question. The main difference in costs between the providing muscle power training and usual care was due to the amount of additional personnel time required. In addition, there may also be some device costs, for example an exercise machine was used in one of the studies included in the clinical review. However, when the cost of the machine is spread over the lifetime of the equipment and the amount of usage, the cost per patient per session is expected to be low. Based on resource use from Cooke (2010 – lower limb strength training intervention)[47] the additional cost of strength training over usual care was estimated to be £1080 and based on Flansbjer (2008 – resistance training intervention)[84] it was estimated to be £1350 (personnel costs only). The GDG considered it likely that strength training would be cost effective as the potential improvement for patients in terms of quality of life from improved function would justify any additional costs of the

	intervention.
Quality of evidence	Many of the studies were limited by small numbers (maximum sample size= 133), some were feasibility studies, inadequately powered and duration of follow-up and time since onset of stroke varied between studies. Because of the wide range of different types of strength training and outcome measures included within the studies it was not possible to carry out any meta-analysis and therefore interpretation of the results was limited. Confidence in the results shown for the majority of the outcomes was low to very low because of study limitations (unclear blinding, unclear randomisation and lack of allocation concealment) and imprecision around the effect estimate. The group agreed it was not clear whether there would be a persistent difference between the groups at 6 months or 1 year. The GDG agreed that it was difficult to determine the treatment effect from the small study sizes presented. The group agreed that there was no clear evidence to show that strength training is better than the control interventions (usual practice) but both strength training and usual practice led to improvements so the consensus of the group was that this strength training is useful for those with weakness in upper or lower limbs, and therefore could be considered as part of a person's rehabilitation.
Other considerations	Definitions of strength training vary from traditional resistance training to functional strength training. Conventional resistance training would include exercises such as lifting weights in a gym, whereas functional strength training focuses on building stamina through a range of tasks such as walking and graded activities delivered by a rehabilitation professional. The nature of strength training varied according to whether it was upper or lower limb and time since onset of the stroke. There was no indication from the studies presented of what dose of strength training is appropriate. It was also highlighted that evidence for strength training which involved a family member showed short term improvements. Yet these were short lived and therefore seem not to make a contribution to long term functional gains.

13.2 Fitness Training

13.2.1 In people after stroke, does cardiorespiratory or resistance fitness training improve outcome (fitness, function, quality of life, mood) and reduce disability?

Clinical Methodological Introduction	
Population	Adults and young people 16 or older who have had a stroke.
Intervention	Any cardiorespiratory or resistance fitness training such as: Aquatic physical exercise Cycle, rowing or treadmill ergometry Weight bearing resistance training Dynamic and isokinetic muscle strength training
Comparison	Usual care (other physiotherapy)
Outcomes	• Mortality rate • Dependence or level of disability • Physical fitness

Clinical Methodological Introduction	
	• Mobility • Physical function • Quality of life • Mood Indices and scales may include: • Blood pressure • Body mass • Maximal oxygen update (peak VO2 (ml/kg/min) • Endurance • Barthel • Rivermead mobility index • SF-36 • EuroQol • HADS • Beck Depression Index • Geriatric depression scale • Epidemiologic studies for depression scale (CES-D)

13.2.1.1 Clinical Evidence Review

Searches were conducted for systematic reviews comparing the clinical effectiveness of fitness training (cardiorespiratory or resistance) with usual care to improve function and reduce disability for adults and young people 16 or older who have had a stroke.

One Cochrane systematic review (Brazzelli 2011 [31]) was identified. This Cochrane review was adapted to address the current protocol (the comparison of mixed cardiorespiratory vs. usual care was removed and outcomes that had already been included in the review in 12.1 were removed from the resistance vs. usual care comparison). The Cochrane review included 32 trials. From these trials (32), 21 trials matching our protocol were included for this review.

A further systematic search was conducted for any trial published since the Cochrane search cut-off (March 2010) and four trials (Globas 2012[94], Holmgren 2010 [113], Jin 2012 [125] and Van De Port 2012[267]) was identified.

In the systematic review the following strategy of analysis was adopted:

- The effects of the interventions were separately analysed at the 'end of the intervention' and at the 'end of follow-up'. 'End of intervention' refers to the time-point when a training programme finishes (ranged from 2 – 14 weeks) and 'end of follow-up' refers to any time-point occurring after the end of intervention (ranged from 12 – 36 weeks). (See individual GRADE Table 92/ Table 93 for cardiorespiratory and Table 94/Table 95 for resistance training). Retained training effects were measured at the end of follow-up.
- Studies were included in which controls were exposed to either physical activity occurring during usual care or 'no training' after usual care. 'No training' refers to no intervention or a non-exercise intervention. These were sub group analyses within each GRADE table
- Cardiorespiratory training was also compared with resistance training using one mobility outcome (see GRADE Table 96)
- When there is an outcome with sub group, overall effects as well as sub-group analyses (in italics) are presented (see GRADE tables)
- The evidence statements also reflect the total effects as well as the sub-group analysis.

Please see Appendix M for excluded trials from the Cochrane review.

Table 90 summarises the population, intervention, comparison and outcomes for each of the studies.

Table 90: Overview of studies included in the Cochrane review

COMPARISON	STUDIES	TOTAL NUMBER OF PARTICIPANTS	RANGE OF INTERVENTIONS	OUTCOMES
Cardiorespiratory vs. usual care	Aidar 2007 [3]; Bateman 2001 [19]; Cuviello-Palmer 1988 [52]; da Cunha 2002 [52]; Eich 2004 [74]; Glasser 1986 [93]; Katz-Leurer 2003 [134]; Lennon 2008 [152]; Moore 2010 [177]; Mudge 2009 [180]; Pohl 2002 [208]; Potempa 1995 [211]; Salbach 2004 [229]; Smith 2008 [244]	718 participants	Two of these trials assessed circuit training (Mudge 2009; Salbach 2004), one trial assessed aquatic training (Aidar 2007), while the remaining trials employed different forms of ergometry (cycle, treadmill or Kinetron)	Disability • Functional Independence Measure (FIM) • Rivermead Mobility Index • Physical Activity and Disability Scale • Nottingham Extended ADL • Frenchay Activities Index Mobility • Functional Ambulation Categories • Maximal gait speed (m/min) • Preferred gait speed (m/min) • 6 Minute Walk Test (metres) • Gait endurance • 6 metre walking time (sec) • Stroke Impact Scale (mobility domain) • Peak activity index (steps/min) • Maximum step rate in 1 min Risk factors • Blood pressure (systolic and Diastolic) Health Related QoL • SF-36 • EuroQoL Mood

COMPARISON	STUDIES	TOTAL NUMBER OF PARTICIPANTS	RANGE OF INTERVENTIONS	OUTCOMES
				• Beck Depression Index • Hospital Anxiety and Depression Scale • Geriatric Depression Scale • Centre for Epidemiologic Studies for Depression Scale Case fatality
Resistance vs. usual care	Bale 2008 [14]; Cooke 2010* [47]; Flansbjer 2008 [84]; Kim 2001 [136]; Ouellette 2004 [195]; Sims 2009 [238]; Winstein 2004 [285]	192 participants	All employed muscle contractions resisted by weights, exercise machines, or elastic devices. Five trials limited the strength training to the lower limbs, one trial to the upper limbs (Winstein 2004), and one trial trained both the upper and lower limbs (Sims 2009).	Physical fitness • Peak VO2 (ml/kg/min) • Gait economy, VO2 (ml/kg/metre) • Maximum cycling work rate (Watts) • Body mass (Kg) • Composite measure of muscle strength • Knee flexion/knee extension (Nm) Physical function • Berg Balance Scale • Timed Up and Go (sec) • Weight bearing (affected side) • Stair climbing, maximal (sec/step)
Cardiorespiratory vs. resistance	Cuviello-Palmer 1988 [52]; Katz-Leurer 2003 [134]; Moore 2010 [177]; Salbach 2004 [229]; Bale 2008 [14]; Kim 2001 [136]; Ouellette 2004 [195]	301 participants	Walking speed	Preferred gait speed (m/min)

** Cooke 2010 was included in the 'mixed cardiovascular-resistance' group which is not in our protocol. However, this study included only resistance training as an intervention and therefore was moved to this comparison in our edited version of the Cochrane review.*

Table 91. Details of four additional RCTs that were completed since the Cochrane review and were added to the current review. See Appendix H for extraction

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Holmgren 2010 [113]	34 patients with stroke. 3-6 months after stroke onset 15 allocated to intervention and 19 allocated to control.	Seven sessions a week divided over 3 days with individualized group training, supervised by a physiotherapist (PT) plus one session a week for 1hr with educational group discussions about fall risk and security aspects led by a PT and an OT (N=15)	One session a week for 1hr each during the 5-week period. Session was an educational group discussion session led by one occupational therapist (OT) (N=19)	• SF-36 • Geriatric Depression Scale-15
Globas 2012[94]	38 patients with stroke (>6 months) aged >60 years with residual hemiparetic gait (at least 1 clinical sign for paresis, spasticity or circumduction of affected leg while walking); ability to walk on treadmill at ≥0.3km/hr. for 3 minutes with handrail support.	High-intensity aerobic treadmill exercise (TAEX) for 3 months (39 sessions) starting with 10-20 minutes at 40-50% heart rate reserve (HRR) building up to 30-50 minutes at 60-80% HRR	Conventional Care Physiotherapy (1-3 sessions of 1 hour each/week) including passive muscle tone-regulating exercises for upper and lower extremity, balance training	• Body-mass adjusted peak VO2; • Sustained walking ability (6 minute walk). 2ry: • 10m timed walk at comfortable and maximal speeds; • 5 chair rise test; • Berg balance scale; • Rivermead Index; • SF-12
Jin 2012 [125]	133 participants age 50 or older; single stroke >6 months ago; independent in ambulation with or without walking aid	Cycling exercise group: 8-week aerobic cycling training + paretic lower limb weights 40 mins./day 5 times a week, target aerobic intensity 50-70% heart rate reserve	Low-intensity over ground walking training 20-30% heart rate reserve. Both groups had balance exercise 30 minutes and supervised stretching 20 minutes	• 6 minute walking distance, • Rivermead Mobility Index. • Knee muscle strength (dynamometer); balance (Berg scale); • Spasticity (Modified Ashworth Scale)
Van De Port 2012[267]	250 participants with verified stroke who had completed inpatient rehabilitation (discharged home) as soon as they were able to start	Task-oriented circuit training: 90 minute graded task-oriented circuit training twice a week for 12 weeks aimed at improving walking competency (warm up 5 minutes;	Usual physiotherapy care for 12 weeks according to guidelines; no restrictions on content, time or duration	• Stroke Impact Scale Mobility domains SIS; RMI, • NEADL, • HADS, • fatigue severity,

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
	outpatient rehabilitation; able to walk a minimum of 10m without physical assistance; need to continue physiotherapy to improve walking competency or physical condition or both; able to give informed consent; motivated to participate in 12 week intensive physiotherapy programme.	circuit training 60 minutes; evaluation/break 10 minutes; group game 15 minutes)		• Motricity Index, • functional ambulation, • 6 min walk, • 5m comfortable walk, • timed balance, • timed up and go,

Comparison: Cardiorespiratory training versus usual care

Table 92: Cardiorespiratory training – end of intervention versus usual care - Clinical study characteristics and clinical summary of findings.

Sub-groups are in italics.

Quality assessment						**Summary of findings**				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
Disability - Functional Independence Measure (Better indicated by higher values)										
3 See sub-groups below (next 4 rows)	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	See sub-groups for means	See sub-groups for means	0.21 (-0.10, 0.52)	SMD 0.21 higher (0.1 lower to 0.52 higher)	Low
Disability - Functional Independence Measure - During usual care (Better indicated by higher values)										
1 Bateman 2001 [19]	RCT- single blind	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(b)	104.74 (17.7)	100.38 (18.92)	0.23 (-0.32, 0.78)	SMD 0.23 higher (0.32 lower to 0.78 higher)	Moderate
Disability - Functional Independence Measure - After usual care (Better indicated by higher values)										

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
2 Cuviello-Palmer 1988 [52]; Katz-Leurer 2003 [134]	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	Cuviello-Palmer: 44.79 (8.77) Katz-Leurer: 105.8(12.5)	Cuviello-Palmer: 47.18 (9.88) Katz-Leurer: 101.4 (16)	0.17 (-0.29, 0.63)	SMD 0.17 higher (0.29 lower to 0.63 higher)	Low
Disability – Rivermead Mobility Index (Better indicated by higher values)										
4 See sub-groups below (next 4 rows)	RCTs- single blind	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(c)	See subgroups below	See subgroups below	0.57 (-0.03, 1.17)	MD 0.57 higher (0.03 lower to 1.17 higher)	Moderate
Disability - Rivermead Mobility Index - During usual care (Better indicated by higher values)										
3 Bateman 2001 [19] Jin 2012[125] Van De Port [267]	RCTs- single blind	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision	Bateman 10.06 (3.6) Jin 10.5 (1.7) Van de Port 13.47 (1.44)	Bateman 9.9 (3.65) Jin 10.4 (1.6) Van de Port 12.82 (1.44)	0.41 (0.01, 0.81)	MD 0.41 higher (0.01 higher to 0.81 higher)	Moderate

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
Disability - Rivermead Mobility Index - After usual care (Better indicated by higher values)										
1 Globas 2012[94]	RCTs- single blind	Serious limitations(d)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	13.3 (1.7)	11.3 (2.7)	2 (0.53, 3.47)	MD 2 higher (0.53 higher to 3.47 higher)	Low
Disability - Physical Activity and Disability Scale - After usual care (Better indicated by lower values)										
1 Mudge 2009 [180]	RCT- single blind	Serious limitations(d)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	77.8 (55.7)	60.9 (67.2)	16.9 (-15.15, 48.95)	MD 16.9 higher (15.15 lower to 48.95 higher)	Low
Risk factors - blood pressure, systolic (Better indicated by lower values)										
4 See sub-groups below (next 4 rows)	RCT- single blind	Serious limitations(a)	Serious inconsistency(e)	No serious indirectness	No serious imprecision	See sub-groups for means	See sub-groups for means	0.4 (-8.38, 9.18)	MD 0.4 higher (8.38 lower to 9.18 higher)	Low
Risk factors - blood pressure, systolic - During usual care (Better indicated by lower values)										

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
1 da Cunha 2002 [53]	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	da Cunha: 191.33 (9.93)	Da Cunha: 165 (28.81)	26.33 (1.95 to 50.71)	MD 26.33 higher (1.95 to 50.71 higher)	Low
Risk factors - blood pressure, systolic - After usual care (Better indicated by lower values)										
3 Katz-Leurer 2003 [134]; Lennon 2008 [152]; Potempa 1995 [211]	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	No serious imprecision	Katz-Leurer: 130.3 (15.7) Lennon: 136 (13.3) Potempa: 127.3 (18.31)	Katz-Leurer: 136.2 (19.5) Lennon: 133.5 (16.7) Potempa: 131.5 (22.54)	-2.69 (-8.03, 2.66)	MD 2.69 lower (8.03 lower to 2.66 higher)	Moderate
Risk factors - blood pressure, diastolic (Better indicated by lower values)										
4 See sub-groups below (next 4 rows)	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	No serious imprecision	See sub-groups for means	See sub-groups for means	-0.33 (-2.97, 2.31)	MD 0.33 lower (2.97 lower to 2.31 higher)	Moderate
Risk factors - blood pressure, diastolic - During usual care (Better indicated by lower values)										

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
1 da Cunha 2002 [53]	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	Very serious imprecision(j)	95.33 (9.69)	94.33 (10.54)	1 (-10.46, 12.46)	MD 1 higher (10.46 lower to 12.46 higher)	Very low
Risk factors - blood pressure, diastolic - After usual care (Better indicated by lower values)										
3 Katz-Leurer 2003 [134]; Lennon 2008 [152]; Potempa 1995 [211]	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	No serious imprecision	Katz-Leurer: 79 (9.7) Lennon: 81.4 (8.4) Potempa: 78.4 (9.15)	Katz-Leurer: 80.8 (10.2) Lennon: 82 (9) Potempa: 76.4 (7.67)	-0.41 (-3.12, 2.31)	MD 0.41 lower (3.12 lower to 2.31 higher)	Moderate
Physical fitness - peak VO2 (ml/kg/min) (Better indicated by higher values)										
6 See sub-groups below (next 4 rows)	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	See sub-groups for means	See sub-groups for means	2.73 (1.29 to 4.17)	MD 2.14 higher (0.5 to 3.78 higher)	Low

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
Physical fitness - peak VO2 (ml/kg/min) - During usual care (Better indicated by higher values)										
2 da Cunha 2002 [53]; Jin 2012[125]	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	No serious imprecision	Da Cunha 11.55 (2.76) Jin 16.8 (1)	Da Cunha 8.12 (2.3) Jin 13.3 (1)	3.50 (3.16, 3.84)	MD 3.50 higher (3.16 to 3.84 higher)	Moderate
Physical fitness - peak VO2 (ml/kg/min) - After usual care (Better indicated by higher values)										
4 Lennon 2008 [152]; Moore 2010 [177]; Potempa 1995 [211]; Globas 2012[94]	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	Lennon: 12 (2.2) Moore: 18 (5.4) Potempa: 18.8 (4.79) Globas 24.4 (6.6)	Lennon: 11.1 (1.9) Moore: 16 (7.1) Potempa: 15.2 (4.32) Globas 20.9 (7.8)	1.85 (0.31, 3.39)	MD 1.85 higher (0.31 to 3.39 higher)	Low
Physical fitness – gait economy, VO2 (ml/kg/metre) – After usual care (Better indicated by higher values)										
1 Moore 2010 [177]	RCT- single blind	Serious limitations(f)	No serious inconsistency	No serious indirectness	Very serious imprecision(g)	0.291 (0.228)	0.371 (0.234)	-0.08 (-0.28, 0.12)	MD 0.08 lower (0.28 lower to	Very low

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
									0.12 higher)	
Physical fitness - maximum cycling work rate (Watts) (Better indicated by higher values)										
4 See sub-groups below (next 4 rows)	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	See sub-groups for means	See sub-groups for means	0.6 (0.18, 1.02	SMD 0.6 higher (0.18 to 1.02 higher)	Low
Physical fitness - maximum cycling work rate (Watts) - During usual care (Better indicated by higher values)										
2 Bateman 2001 [19]; da Cunha 2002 [53]	RCT- single blind	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(c)	Bateman: 4.22 (0.72) da Cunha: 62.5 (26.22)	Bateman: 4.13 (0.59) Da Cunha: 41.67 (12.91)	0.32 (-0.34, 0.98)	SMD 0.32 higher (0.34 lower to 0.98 higher)	Moderate
Physical fitness - maximum cycling work rate (Watts) - After usual care (Better indicated by higher values)										
2 Katz-Leurer 2003 [134];	RCT- single blind	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	Katz-Leurer: 25.2 (14.9) Potempa: 94.2 (46.64)	Katz-Leurer: 12.9 (12.6) Potempa: 66.1 (30.69)	0.83 (0.47 to 1.18)	SMD 0.83 higher (0.47 to 1.18 higher)	Low

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
Potempa 1995 [211]										
Physical fitness – During usual care Body Mass (Kg) (Better indicated by lower values)										
1 Bateman 2001 [19]	RCT- single blind	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(c)	80.79 (15.78)	75.41 (14.58)	5.38 (-1.69, 12.45)	MD 5.38 higher (1.69 lower to 12.45 higher)	Moderate
Mobility - functional ambulation categories - During usual care (Better indicated by higher values)										
3 da Cunha 2002 [53]; Pohl 2002 [208]; Pohl 2002 [208]*Van de Port[267]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	da Cunha: 2.33 (1.37) Pohl: 5 (0.01) Pohl*: 4.6 (0.6) Van de Port 4.87 (0.36)	Da Cunha: 1.86 (1.77) Pohl: 4.3 (0.7) Pohl*: 4.3 (0.7) Van de Port 4.74 (0.55)	0.33[0.01, 0.65]	MD 0.33 higher (0.01 to 0.65 higher)	Low
Mobility - maximal gait speed (m/min over 5 to 10 metres) (Better indicated by higher values)										
7 See sub-	RCT- single blind	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(f)	See sub-groups for means	See sub-groups for	8.66 (2.98,	MD 8.66 higher	Moderate

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
groups below (next 4 rows)							means	14.34)	(2.98 to 14.34 higher)	
Mobility - maximal gait speed (m/min over 5 to 10 metres) - During usual care (Better indicated by higher values)										
4 da Cunha 2002 [53]; Pohl 2002 [208]*; Bateman 2001 [19]; Eich 2004 [74]; Pohl 2002 [208]	RCT- single blind	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(f)	da Cunha: 35.5 (17.4) Pohl*: 73.2 (44.4) Bateman: 16 (11.06) Eich:42.6 (18) Pohl: 97.8 (48)	da Cunha: 16.2 (13.8) Pohl*: 58.2 (38.4) Bateman: 16.22 (19.49) Eich: 36 (13.2) Pohl: 58.2 (38.4)	10 (-0.05, 20.05	MD 10 higher (0.05 lower to 20.05 higher)	Moderate
Mobility - maximal gait speed (m/min over 5 to 10 metres) - After usual care (Better indicated by higher values)										
3 Salbach 2004 [229];	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(f)	Salbach: 59.4 (33.6)	Salbach: 48 (29.4) Moore: 46.2	9.93 (3.38, 16.48)	MD 9.93 higher (3.38 to	Low

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
Moore 2010 [177]; Mudge 2009 [180]						Moore: 54.6 (26.4) Mudge: 47.4 (16.8)	(19.2) Mudge: 37.8 (15)		16.48 higher)	
Mobility - preferred gait speed (m/min) (Better indicated by higher values)										
4 See sub-groups below (next 4 rows)	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	No serious imprecision	See sub-groups for means	See sub-groups for means	4.68 (1.4, 7.96)	MD 4.68 higher (1.4 to 7.96 higher)	Moderate
Mobility - preferred gait speed (m/min) - During usual care (Better indicated by higher values)										
1 Cuviello-Palmer 1988 [52]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(f)	18.11 (9.22)	12.07 (6.41)	6.04 (-0.92, 13)	MD 6.04 higher (0.92 lower to 13 higher)	Low
Mobility - preferred gait speed (m/min) - After usual care (Better indicated by higher values)										
3 Katz-Leurer	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	No serious imprecision	Katz-Leurer: 30.6 (10.8) Moore: 37.8 (18)	Katz-Leurer: 27 (9.6) Moore: 34.8	29 (0.57, 8.01)	MD 4.29 higher (0.57 to	Moderate

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
2003 [134]; Moore 2010 [177]; Salbach 2004 [229]						Salbach: 46.8 (24)	(13.8) Salbach: 38.4 (22.2)		8.01 higher)	
Mobility - gait endurance (6-MWT metres) (Better indicated by higher values)										
7 See sub-groups below (next 4 rows)	RCT- single blind	Serious limitation(a)	Serious inconsistency()	No serious indirectness	Serious imprecision(n)	See sub-groups for means	See sub-groups for means	39.39 (13.53, 65.25)	MD 39.39 higher (13.53 to 65.25 higher)	Very Low
Mobility - gait endurance (6-MWT metres) - During usual care (Better indicated by higher values)										
3 Eich 2004 [74]; Jin 2012[125] van de Port 2012[267]	RCT- single blind	Serious limitation	Very serious inconsistency(h)	No serious indirectness	Serious imprecision(n)	Eich 198.8 (81.1) Jin 218.5 (63.7) Van de Port 412 (117)	Eich 164.4 (69.3) Jin 213.5 (50.6) Van de Port 354 (145)	30.25 (-4.70, 65.21)	MD 30.25 higher (4.70 lower to 65.21higher)	Very low
Mobility - gait endurance (6-MWT metres) - After usual care (Better indicated by higher values)										

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
4 Moore 2010 [177]; Mudge 2009 [180]; Salbach 2004 [229]; Globas 2012[94]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(n)	Moore: 226 (130) Mudge: 282 (117) Salbach:249 (136) Globas 332.1 (138)	Moore: 201 (134) Mudge: 200 (99) Salbach:209 (132) Globas 265.9 (189)	58.10 (23.02, 93.17)	MD 58.10 higher (23.02 to 93.17 higher)	Low
Mobility – maximal gait speed (m/sec over 10 metres) - After usual care (Better indicated by higher values)										
1 Globas 2012 [94]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(f)	1.02 (0.38)	0.87 (0.62)	0.15 (-0.19, 0.49)	MD 0.15 lower (0.19 lower to 0.49 higher)	Low
Mobility – comfortable gait speed (m/sec over 5 to 10 metres) - (Better indicated by higher values)										
2 See subgroups below	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(f)	See subgroups below	See subgroups below	0.20 (0.12, 0.28)	MD 0.20 higher (0.12 to 0.28	Low

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
									higher)	
Mobility – comfortable gait speed (m/sec over 10 metres) – During usual care (Better indicated by higher values)										
Van de Port 2012[267]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(f)	1.1(0.3)	0.89 (0.36)	0.21 (0.13, 0.29)	MD 0.21 higher (0.13 to 0.29 higher)	Low
Mobility – comfortable gait speed (m/sec over 10 metres) - After usual care (Better indicated by higher values)										
1 Globas 2012 [94]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(f)	0.79 (0.29)	0.70 (0.46)	0.09 (-0.16, 0.34)	MD 0.09 higher (0.16 lower to 0.34 higher)	Low
Mobility - gait endurance (m/min) (Better indicated by higher values)										
3 See sub-groups below (next 4 rows)	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(h)	See sub-groups for means	See sub-groups for means	8.87 (1.35, 16.4)	MD 8.87 higher (1.35 to 16.4 higher)	Low
Mobility - gait endurance (m/min) - During usual care (Better indicated by higher values)										

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
2 da Cunha 2002 [53]; Eich 2004 [74]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(h)	da Cunha: 34.17 (17.17) Eich: 33.13 (13.52)	da Cunha: 12.14 (10.87) Eich: 27.4 (11.55)	12.24 (-3.41, 27.89)	MD 12.24 higher (3.41 lower to 27.89 higher)	Moderate
Mobility - gait endurance (m/min) - After usual care (Better indicated by higher values)										
1 Salbach 2004 [229]	RCT- single blind	Serious limitation(c)	No serious inconsistency	No serious indirectness	Serious imprecision(h)	41.4 (22.8)	34.8 (22.2)	6.6 (-2.66, 15.86)	MD 6.6 higher (2.66 lower to 15.86 higher)	Low
Mobility - 6-metre walking time (sec) - During usual care (Better indicated by lower values)										
1 Glasser 1986 [93]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(i)	9.98 (3.03)	13.3 (7.82)	-3.32 (-8.52, 1.88)	MD 3.32 lower (8.52 lower to 1.88 higher)	Low
Mobility - Stroke Impact Scale (mobility domain) (Better indicated by lower values)										
2 See		No serious	No serious	No serious	Serious	See subgroups	See	3.20	MD 3.20	Moderate

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
subgroups below		limitation	inconsistency	indirectness	imprecision(c)	below	subgroups below	(0.04, 6.35	(0.04 to 6.35 higher)	
Mobility - Stroke Impact Scale (mobility domain) - During usual care (Better indicated by lower values)										
1 Van de Port 2012 [267]	RCT- single blind	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(c)	87.27 (12.38)	83.73 (13.25)	3.54 (0.30, 6.78)	MD 3.54 higher (0.30 to 6.78 higher)	Moderate
Mobility - Stroke Impact Scale (mobility domain) - After usual care (Better indicated by lower values)										
1 Smith 2008 [244]	RCT- single blind	Very serious limitations(a)	No serious inconsistency	No serious indirectness	Very serious imprecision(g)	64.8 (16.4)	68 (15.4)	-3.2 (-17.14, 10.74)	MD 3.2 lower (17.14 lower to 10.74 higher)	Very low
Mobility - peak activity index (steps/min) - After usual care (Better indicated by higher values)										
1 Mudge 2009 [180]	RCT- single blind	Serious limitation(d	No serious inconsistency	No serious indirectness	Serious imprecision(c)	67.1 (22.8)	49 (17.5)	18.1 (7.71, 28.49)	MD 18.1 higher (7.71 to 28.49 higher)	Low

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
Mobility - max step rate in 1 min - After usual care (Better indicated by higher values)										
1 Mudge 2009 [180]	RCT- single blind	Serious limitation(d)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	90.7 (21.9)	75.2 (20.5)	15.5 (4.58, 26.42)	MD 15.5 higher (4.58 to 26.42 higher)	Low
Physical function - Berg Balance scale (Better indicated by higher values)										
5 See sub-group below (next 4 rows)	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	See sub-group for means	See sub-group for means	1.28 (-1.74, 3.30)	MD 1.28 higher (1.74 lower to 3.30 higher)	Low
Physical function - Berg Balance scale - During usual care (Better indicated by higher values)										
2 Bateman 2001 [19]; Jin 2012[125]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	No serious imprecision	Bateman 45 (11.9) Jin 48.6 (2.9)	Bateman 45.3 (11.3) Jin 48.3 (3.9)	0.27 (-0.87, 1.41)	MD 0.27 higher (0.87 lower to 1.41 higher)	Moderate
Physical function - Berg Balance scale - After usual care (Better indicated by higher values)										
3	RCT- single	Serious	No serious	No serious	Serious	Moore: 48 (10)	Moore: 46	4.06	MD 4.06	Low

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
Moore 2010 [177]; Salbach 2004 [229]; Globas 2012[94]	blind	limitation(a)	inconsistency	indirectness	imprecision(c)	Salbach: 44 (11) Globas 51.1 (6.4)	(10) Salbach: 41 (13) Globas 44.3 (11.9)	(0.52, 7.60)	higher (o.52 to 7.60 higher)	
Physical function - Timed Up and Go (sec) (Better indicated by lower values)										
3 See subgroups below	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	See subgroups below	See subgroups below	-3.99 (-6.91, -1.08)	MD 3.99 lower (6.91 to 1.08 lower)	High
Physical function - Timed Up and Go (sec) - During usual care (Better indicated by lower values)										
1 Van de Port 2012[267]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	11 (7)	15 (16)	-4.00 (-7.15, -0.85)	MD 4.00 lower (7.15 to 0.85 lower)	High
Physical function - Timed Up and Go (sec) - After usual care (Better indicated by lower values)										
2 Moore 2010 [177];	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(j)	Moore: 20 (12) Salbach: 23.2 (20.6)	Moore: 24 (16) Salbach:	-3.94 (-11.65, 3.77)	MD 3.94 lower (11.65	Low

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
Salbach 2004 [229]							27.1 (27.1)		lower to 3.77 higher)	
Health related QoL - SF-36 or SF- 12physical functioning - After usual care (Better indicated by higher values)										
3 Aidar 2007 [3]; Globas 2012[94]; Holmgren 2010 [113]	RCT- single blind	Serious limitation(a)	Very serious inconsistency(k)	No serious indirectness	Serious imprecision(c)	Aidar 69.9 (3.2) Globas 46.5 (5) Holmgren 52.1 (22.2)	Aidar 59.3 (6.9) Globas 43.7 (8.3) Holmgren 45.8. (26.6)	0.82 (-0.13, 1.77)	SMD 0.82 higher (0.13 lower to 1.77 higher)	Very low
Health related QoL - SF-36 emotional role functioning - After usual care (Better indicated by higher values)										
1 Aidar 2007 [3]	RCT- single blind	Very serious limitation(a)	No serious inconsistency	No serious indirectness	No serious imprecision	69.2 (3.5)	58.2 (8.3)	11 (6.15, 15.85)	MD 11 higher (6.15 to 15.85 higher)	Low
Health related QoL - SF-36 emotional role functioning - Post intervention (Better indicated by higher values)										
1 Holmgren 2010 [113]	RCT- single blind	Serious limitation(d)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	71.4 (38.9)	86 (32)	-14.6 (-39.54, 10.34)	MD 14.6 lower (39.54 lower to	Low

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
									10.34 higher)	
Health related QoL - SF-36 mental health - Post intervention (Better indicated by higher values)										
1 Holmgren 2010 [113]	RCT- single blind	Serious limitation(d)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	86.4 (12.4)	79.4 (20.8)	5.2 (-6.19, 16.59)	MD 5.2 higher (6.19 lower to 16.59 higher)	Low
Health related QoL - SF-36 Physical Component Scale - Post intervention (Better indicated by higher values)										
1 Holmgren 2010 [113]	RCT- single blind	Serious limitation(d)	No serious inconsistency	No serious indirectness	Very serious imprecision(g)	32.2 (10.6)	33.2 (12)	-1 (-8.74, 6.74)	MD 1 lower (8.74 lower to 6.74 higher)	Very low
Health related QoL - SF-36 Mental Component Scale - Post intervention (Better indicated by higher values)										
1 Holmgren 2010 [113]	RCT- single blind	Serious limitation(d)	No serious inconsistency	No serious indirectness	Very serious imprecision(g)	54.4 (10.3)	54.8 (10)	-0.4 (-7.42, 6.62)	MD 0.4 lower (7.42 lower to 6.62	Very low

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
									higher)	
Mood - Beck Depression Index - After usual care (Better indicated by lower values)										
1 Smith 2008 [244]	RCT- single blind	Very serious limitation(a)	No serious inconsistency	No serious indirectness	Very serious imprecision(g)	9.4 (1.9)	8.8 (3)	0.6 (-1.6, 2.8)	MD 0.6 higher (1.6 lower to 2.8 higher)	Very low
Mood - Hospital Anxiety and Depression Scale (HADS) - anxiety score - During usual care (Better indicated by lower values)										
2 Bateman 2001 [19]; Van de Port 2012[267]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(c)	Bateman 4.42 (3.69) Van de Port 3.8 (3.4)	6.36 (3.47) Van de Port 4.01 (3.6)	-0.87 (-2.52, 0.78)	MD 0.78 lower (2.58 lower to 078 higher)	Moderate
Mood - Hospital Anxiety and Depression Scale (HADS) and Geriatric Depression score - depression - (Better indicated by lower values)										
1 Bateman 2001 [19] Van de Port 2012[267];	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	serious imprecision	Bateman 5.54 (3.26) Van de Port 4.92 (3.62)	Bateman 6.94 (3.82) Van de Port 4.42 (3.69)	-0.25 (-0.77, 0.27)	SMD 0.25 lower 0.77 lower to 0.27 higher)	Moderate

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) /Standardised Mean Difference (SMD) (95% CI)	
Holmgren 2010 [113]										

(a) Unclear allocation concealment and blinding (outcome assessor). Limitations were considered by study weights in the meta-analysis
(b) Mean difference did not reach the agreed MID of 17 points for the motor scale between the intervention and control group
(c) Confidence interval crosses default MID (0.5) for single studies or default 0.5*median control SD for 2 or more studies
(d) Unclear allocation concealment
(e) Heterogeneity: I^2 = 59%
(f) Unclear blinding (outcome assessor)
(g) Confidence interval crosses both ends of default MID (0.5) for single studies or default 0.5*(median control SD) for 2 or more studies
(h) Mean difference did not reach agreed MID of 0.16m/sec for the walking speed between the intervention and control group for acute stroke patients or 0.2 m/sec for chronic stroke patients
(i) Mean difference did not reach agreed MID of 28m for the 6 MWT between the intervention and control group
(j) Mean difference did not reach the agreed MID of 10 secs. for the Time Up and Go between the intervention and control group
(k) Heterogeneity: I^2 = 74%
(l) Pohl 2002*: Pohl 2002 data were subdivided into two relevant comparisons. Half of the controls (10 participants) were used for each comparison

Comparison: Cardiorespiratory training versus usual care

Table 93: Cardiorespiratory training – end of retention follow-up versus usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of retention follow-up Mean (SD)/ Frequency	Usual care Mean (SD)/ Frequency	Effect		Confidence (in effect)
								Relative risk/ mean difference (95% CI)	Absolute effect / Mean difference (MD) (95% CI)	
Case fatality										
1 Katz-Leurer 2003 [134]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Very serious imprecision(b)	1/42 (2.40%)	2/39 (5.10%)	0.46 (0.04, 4.92)	28 fewer per 1000 (from 49 fewer to 201 more)	Very low
Disability - Rivermead Mobility Index - During usual care (Better indicated by higher values)										
1 Bateman 2001 [19]	RCT- single blind	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(c)	10.72 (3.3)	10.97 (3.35)	-0.25 (-1.85, 1.35)	MD 0.25 lower (1.85 lower to 1.35 higher)	Moderate
Disability - Nottinghan Extended ADLs - During usual care (Better indicated by higher values)										
1 Bateman 2001 [19]	RCT- single blind	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(c)	34.23 (16.3)	31.59 (17.17)	2.64 (-5.57, 10.85)	MD 2.64 higher (5.57 lower to 10.85 higher)	Moderate

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of retention follow-up Mean (SD)/ Frequency	Usual care Mean (SD)/ Frequency	Effect		Confidence (in effect)
								Relative risk/ mean difference (95% CI)	Absolute effect / Mean difference (MD) (95% CI)	
Disability - Physical Activity and Disability Scale – After usual care (Better indicated by lower values)										
1 Mudge 2009 [180]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	82.1 (72.8)	62.2 (72.5)	19.9 (-17.58, 57.38)	MD 19.9 higher (17.58 lower to 57.38 higher)	Low
Disability - Frenchay Activities Index (FAI) - After usual care (Better indicated by higher values)										
1 Katz-Leurer 2003 [134]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	27 (6.5)	26 (5)	1 (-1.55, 3.55)	MD 1 higher (1.55 lower to 3.55 higher)	Low
Physical fitness - maximum cycling work rate (Watts) - During usual care (Better indicated by higher values)										
1 Bateman 2001 [19]	RCT- single blind	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(c)	84.06 (75.52)	77.94 (44.76)	6.12 (-24.06, 36.3)	MD 6.12 higher (24.06 lower to 36.3 higher)	Moderate
Physical fitness - Body Mass (Kg) - During usual care (Better indicated by lower values)										
1 Bateman 2001 [19]	RCT- single blind	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(c)	80.39 (15.83)	77.58 (14.43)	2.81 (-4.63, 10.25)	MD 2.81 higher (4.63	Moderate

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of retention follow-up Mean (SD)/ Frequency	Usual care Mean (SD)/ Frequency	Effect		Confidence (in effect)
								Relative risk/ mean difference (95% CI)	Absolute effect / Mean difference (MD) (95% CI)	
									lower to 10.25 higher)	
Mobility - maximal gait speed (m/min) (Better indicated by higher values)										
3 See sub-groups below (next 4 rows)	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(d)	See sub-groups for means	See sub-groups for means	8.21 (3.38, 13.05)	MD 8.21 higher (3.38 to 13.05 higher)	Moderate
Mobility - maximal gait speed (m/min) - During usual care (Better indicated by higher values)										
2 Bateman 2001 [19]; Eich 2004 [74]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(d)	Bateman: 21.04 (12.31) Eich: 46.2 (21)	Bateman: 15 (21.86) Eich: 34.8 (13.2)	8.1 (1.98, 14.22)	MD 8.1 higher (1.98 to 14.22 higher)	Moderate
Mobility - maximal gait speed (m/min) - After usual care (Better indicated by higher values)										
1 Mudge 2009 [180]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(d)	46.2 (15.6)	37.8 (15)	8.4 (0.52, 16.28)	MD 8.4 higher (0.52 to 16.28 higher)	Low
Mobility - gait endurance (6-MWT metres) (Better indicated by lower values)										
2	RCT- single	No serious	No serious	No serious	No serious	See sub-groups for	See sub-	69.3	MD 69.3	High

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of retention follow-up Mean (SD)/ Frequency	Usual care Mean (SD)/ Frequency	Effect		Confidence (in effect)
								Relative risk/ mean difference (95% CI)	Absolute effect / Mean difference (MD) (95% CI)	
See sub-groups below (next 4 rows)	blind	limitation	inconsistency	indirectness	imprecision	means	groups for means	(33.38, 105.23)	higher (33.38 to 105.23 higher)	
Mobility - gait endurance (6-MWT metres) - During usual care (Better indicated by higher values)										
1 Eich 2004 [74]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(f)	224.8 (90)	163 (70.2)	61.8 (16.48, 107.12)	MD 61.8 higher (16.48 to 107.12 higher)	Moderate
Mobility - gait endurance (6-MWT metres) - After usual care (Better indicated by higher values)										
1 Mudge 2009 [180]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(f)	277 (125)	195 (104)	82 (23.05, 140.95)	MD 82 higher (23.05 to 140.95 higher)	Low
Mobility - peak activity index (steps/min) - After usual care (Better indicated by higher values)										
1 Mudge 2009 [180]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	63.7 (21.5)	51.5 (20.5)	12.2 (1.38, 23.02)	MD 12.2 higher (1.38 to 23.02 higher)	Low
Mobility - max step rate in 1 min - After usual care (Better indicated by higher values)										

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of retention follow-up Mean (SD)/ Frequency	Usual care Mean (SD)/ Frequency	Effect		Confidence (in effect)
								Relative risk/ mean difference (95% CI)	Absolute effect / Mean difference (MD) (95% CI)	
1 Mudge 2009 [180]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	87.7 (21)	75.6 (22.2)	12.1 (0.93, 23.27)	MD 12.1 higher (0.93 to 23.27 higher)	Low
Mobility - Stroke Impact Scale (mobility domain) - After usual care (Better indicated by lower values)										
1 Smith 2008 [244]	RCT- single blind	Very serious limitation(a)	No serious inconsistency	No serious indirectness	Very serious imprecision(e)	78.3 (13.3)	72.4 (18)	5.9 (-7.97, 19.77)	MD 5.9 higher (7.97 lower to 19.77 higher)	Very low
Physical function - Berg Balance scale - During usual care (Better indicated by higher values)										
1 Bateman 2001 [19]	RCT- single blind	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(c)	46.16 (12.09)	49.09 (8.01)	-2.93 (-7.91, 2.05)	MD 2.93 lower (7.91 lower to 2.05 higher)	Moderate
Mood - Beck Depression Index - After usual care (Better indicated by lower values)										
1 Smith 2008 [244]	RCT- single blind	Very serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	7.3 (2.5)	8.6 (2.9)	-1.3 (-3.67, 1.07)	MD 1.3 lower (3.67 lower to 1.07	Very low

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of retention follow-up Mean (SD)/ Frequency	Usual care Mean (SD)/ Frequency	Effect		Confidence (in effect)
								Relative risk/ mean difference (95% CI)	Absolute effect / Mean difference (MD) (95% CI)	
									higher)	
Mood - Hospital Anxiety and Depression Scale (HADS) - anxiety score - During usual care (Better indicated by lower values)										
1 Bateman 2001 [19]	RCT- single blind	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(c)	3.57 (3.36)	5.17 (3.99)	-1.6 (-3.58, 0.38)	MD 1.6 lower (3.58 lower to 0.38 higher)	Moderate
Mood - Hospital Anxiety and Depression Scale (HADS) - depression score - During usual care (Better indicated by lower values)										
1 Bateman 2001 [19]	RCT- single blind	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(c)	3.3 (2.36)	6 (3.92)	-2.7 (-4.4, -1)	MD 2.7 lower (4.4 to 1 lower)	Moderate
Health related QoL - SF-36 Physical Component Scale - 6 months post-intervention (Better indicated by higher values)										
1 Holmgren 2010 [113]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Very serious imprecision(e)	35.3 (13.3)	35.4 (12.9)	-0.1 (-9.47, 9.27)	MD 0.1 lower (9.47 lower to 9.27 higher)	Very low
Health related QoL - SF-36 Mental Component Scale - 6 months post-intervention (Better indicated by higher values)										
1 Holmgren 2010 [113]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	50.4 (15)	55.4 (9.3)	-5 (-14.22, 4.22)	MD 5 lower (14.22 lower to	Low

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of retention follow-up Mean (SD)/ Frequency	Usual care Mean (SD)/ Frequency	Effect		Confidence (in effect)
								Relative risk/ mean difference (95% CI)	Absolute effect / Mean difference (MD) (95% CI)	
									4.22 higher)	
Health related QoL - SF-36 physical functioning - 6 months post-intervention (Better indicated by lower values)										
1 Holmgren 2010 [113]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Very serious imprecision(e)	51.5 (18.6)	46.7 (26.9)	4.8 (-11.22, 20.82)	MD 4.8 higher (11.22 lower to 20.82 higher)	Very low
Health related QoL - SF-36 emotional role functioning - 6 months post-intervention (Better indicated by lower values)										
1 Holmgren 2010 [113]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	71.8 (40.5)	90.7 (27.6)	-18.9 (-44.34, 6.54)	MD 18.9 lower (44.34 lower to 6.54 higher)	Low
Health related QoL - SF-36 mental health - 6 months post-intervention (Better indicated by lower values)										
1 Holmgren 2010	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Very serious imprecision(c)	81.2 (11.9)	77.3 (21.2)	3.9 (-7.84, 15.64)	MD 3.9 higher (7.84 lower to 15.64 higher)	Very low
Mood - Geriatric Depression Scale - 15 - 6 months post-intervention (Better indicated by lower values)										
1	RCT- single	Serious	No serious	No serious	Serious	3 (1.5)	3.7 (2.9)	-0.7 (-2.27,	MD 0.7	Low

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory training - end of retention follow-up Mean (SD)/ Frequency	Usual care Mean (SD)/ Frequency	Effect		Confidence (in effect)
								Relative risk/ mean difference (95% CI)	Absolute effect / Mean difference (MD) (95% CI)	
Holmgren 2010	blind	limitation(a)	inconsistency	indirectness	imprecision(c)			0.87)	lower (2.27 lower to 0.87 higher)	

(a) Unclear allocation concealment/unclear assessor blinding. Limitations were considered by study weights in the meta-analysis
(b) Confidence interval crosses one end of default MID (0.75, 1.25)
(c) Confidence interval crosses one end of default MID (0.5)
(d) Mean difference did not reach agreed MID of 0.16m/sec for the walking speed between the intervention and control group
(e) Confidence interval crosses both ends of default MID (0.5)
(f) Mean difference did not reach agreed MID of 28m for the 6 MWT between the intervention and control group

Comparison: Resistance training versus usual care

Table 94: Resistance training - end of intervention versus usual care- Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Resistance training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean or Standardised Mean Difference (95% CI)	Mean Difference (MD) / Standardised Mean Difference (SMD) (95% CI)	
Physical fitness - composite measure of muscle strength (Better indicated by higher values)										
2 See sub-group below (next 4 rows)	RCT- single and double blind	Serious limitation(d)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	See sub-group for means	See sub-group for means	0.58 (0.06, 1.1)	SMD 0.58 higher (0.06 to 1.1 higher)	Low
Physical fitness - composite measure of muscle strength - During and after usual care (Better indicated by higher values)										
1 Winstein 2004 [285]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	353.53 (296.25)	220.58 (260.26)	0.47 (-0.16, 1.1)	SMD 0.47 higher (0.16 lower to 1.1 higher)	Low
Physical fitness - composite measure of muscle strength - After usual care (Better indicated by higher values)										
1 Kim 2001 [136]	RCT- double blind	Serious limitation(c)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	507 (559)	142 (193)	0.84 (-0.09, 1.76)	SMD 0.84 higher (0.09 lower to 1.76	Low

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Resistance training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean or Standardised Mean Difference (95% CI)	Mean Difference (MD) / Standardised Mean Difference (SMD) (95% CI)	
									higher)	
Physical fitness - muscle strength, knee extension (Nm) (Better indicated by higher values)										
2 See sub-group below (next 4 rows)	RCT- single blind	Very serious limitation(c)	No serious inconsistency	No serious indirectness	Serious imprecision(e)	See sub-group for means	See sub-group for means	12.01 (-4.46, 28.47)	MD 12.01 higher (4.46 lower to 28.47 higher)	Very low
Physical fitness - muscle strength, knee extension (Nm) - During usual care (Better indicated by higher values)										
1 Bale 2008 [14]	RCT- single blind	Very serious limitation(c)	No serious inconsistency	No serious indirectness	Serious imprecision(e)	17.7 (9.8)	12.9 (13.5)	4.8 (-5.98, 15.58)	MD 4.8 higher (5.98 lower to 15.58 higher)	Very low
Physical fitness - muscle strength, knee extension (Nm) - After usual care (Better indicated by higher values)										
1 Flansbjer 2008 [84]	RCT- single blind	Serious limitation(c)	No serious inconsistency	No serious indirectness	Serious imprecision(e)	63.1 (19.6)	41.3 (20.9)	21.8 (4.92, 38.68)	MD 21.8 higher (4.92 to 38.68 higher)	Low
Physical fitness - muscle strength, knee flexion (Nm) (Better indicated by higher values)										

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Resistance training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean or Standardised Mean Difference (95% CI)	Mean Difference (MD) / Standardised Mean Difference (SMD) (95% CI)	
2 See sub-group below (next 4 rows)	RCT- single blind	Very serious limitation(c)	No serious inconsistency	No serious indirectness	Serious imprecision(f)	See sub-group for means	See sub-group for means	9.61 (-5.01, 24.24)	MD 9.61 higher (5.01 lower to 24.24 higher)	Very low
Physical fitness - muscle strength, knee flexion (Nm) - During usual care (Better indicated by higher values)										
1 Bale 2008 [14]	RCT- single blind	Very serious limitation(c)	No serious inconsistency	No serious indirectness	Serious imprecision(f)	7.3 (6.9)	2.8 (4.8)	4.5 (-1.13, 10.13)	MD 4.5 higher (1.13 lower to 10.13 higher)	Very low
Physical fitness - muscle strength, knee flexion (Nm) - After usual care (Better indicated by higher values)										
1 Flansbjer 2008 [84]	RCT- single blind	Serious limitation(c)	No serious inconsistency	No serious indirectness	Serious imprecision(f)	74 (27.7)	53.5 (21.1)	20.5 (0.84, 40.16)	MD 20.5 higher (0.84 to 40.16 higher)	Low
Mobility - maximal gait speed (m/min) (Better indicated by higher values)										
2 See sub-group	RCT- single blind	Very serious limitation(c)	No serious inconsistency	No serious indirectness	Serious imprecision(g)	See sub-group for means	See sub-group for means	3.98 (-4.88, 12.85)	MD 3.98 higher (4.88	Very low

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Resistance training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean or Standardised Mean Difference (95% CI)	Mean Difference (MD) / Standardised Mean Difference (SMD) (95% CI)	
below (next 4 rows)									lower to 12.85 higher)	
Mobility - maximal gait speed (m/min) - During usual care (Better indicated by higher values)										
1 Bale 2008 [14]	RCT- single blind	Very serious limitation(c)	Very serious inconsistency(j)	No serious indirectness	Serious imprecision(g)	17.4 (6)	9 (6)	8.4 (2.82, 13.98)	MD 8.4 higher (2.82 to 13.98 higher)	Very low
Mobility - maximal gait speed (m/min) - After usual care (Better indicated by higher values)										
1 Flansbjer 2008 [84]	RCT- single blind	Serious limitation(c)	No serious inconsistency	No serious indirectness	Serious imprecision(g)	3.98 (7.89)	4.63 (7.29)	-0.65 (-6.86, 5.56)	MD 0.65 lower (6.86 lower to 5.56 higher)	Low
Mobility - preferred gait speed (m/min) - During usual care (Better indicated by higher values)										
1 Bale 2008 [14]	RCT- single blind	Very serious limitation(c)	No serious inconsistency	No serious indirectness	Serious imprecision(g)	13.8 (6)	4.8 (6)	9 (3.42, 14.58)	MD 9 higher (3.42 to 14.58 higher)	Very low
Mobility - Rivermead (Better indicated by higher values)										

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Resistance training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean or Standardised Mean Difference (95% CI)	Mean Difference (MD) / Standardised Mean Difference (SMD) (95% CI)	
1 Cooke 2010 [47]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(b)	37.7 (8.6)	34.6 (10.8)	3.1 (-1.58, 7.78)	MD 3.1 higher (1.58 lower to 7.78 higher)	Moderate
Physical function - weight-bearing (% body weight - affected side) - During usual care (Better indicated by higher values)										
1 Bale 2008 [14]	RCT- single blind	Very serious limitation(c)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	17.4 (8.8)	5.6 (14.6)	11.8 (0.89, 22.71)	MD 11.8 higher (0.89 to 22.71 higher)	Very low
Physical function - stair climbing, maximal (sec/step) - After usual care (Better indicated by higher values)										
2 Kim 2001 [136]; Ouellette 2004 [195]	RCT- single and double blind	Serious limitation(c)	Serious inconsistency(k)	No serious indirectness	Very serious imprecision(h)	Kim:0.03 (0.08) Ouellette:0.65 (0.41)	Kim:0.08 (0.1) Ouellette:0.53 (0.34)	-0.04 (-0.86, 0.77)	SMD 0.04 lower (0.86 lower to 0.77 higher)	Very low
Physical function - Timed Up and Go (sec) - After usual care (Better indicated by higher values)										
1 Flansbjer 2008 [84]	RCT- single blind	Serious limitation(c)	No serious inconsistency	No serious indirectness	Serious imprecision(i)	23.1 (10.3)	24.3 (14.2)	-1.2 (-11.84, 9.44)	MD 1.2 lower (11.84	Low

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Resistance training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean or Standardised Mean Difference (95% CI)	Mean Difference (MD) / Standardised Mean Difference (SMD) (95% CI)	
									lower to 9.44 higher)	
Health related QoL - SF-36 physical functioning - After usual care (Better indicated by higher values)										
1 Kim 2001 [136]	RCT- double blinded	Serious limitation(c)	No serious inconsistency	No serious indirectness	Very serious imprecision(h)	0.74 (7.15)	-0.73 (5.81)	1.47 (-4.24, 7.18)	MD 1.47 higher (4.24 lower to 7.18 higher)	Very low
Health related QoL - SF-36 mental health - After usual care (Better indicated by higher values)										
1 Kim 2001 [136]	RCT- double blinded	Serious limitation(c)	No serious inconsistency	No serious indirectness	Very serious imprecision(h)	1.73 (7.34)	-1.07 (10.13)	2.8 (-4.95, 10.55)	MD 2.8 higher (4.95 lower to 10.55 higher)	Very low
EuroQol Self-perceived health (Better indicated by higher values)										
1 Cooke 2010 [47]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(b)	69.9 (18.9)	60.8 (19.6)	9.1 (-0.14, 18.34)	MD 9.1 higher (0.14 lower to 18.34	Moderate

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Resistance training - end of intervention Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean or Standardised Mean Difference (95% CI)	Mean Difference (MD) / Standardised Mean Difference (SMD) (95% CI)	
									higher)	
Mood - Centre for Epidemiologic Studies for Depression scale (CES-D) - After usual care (Better indicated by lower values)										
1 Sims 2009 [238]	RCT- single blind	Very serious limitation(a); (c)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	15.13 (8.49)	20.62 (11.79)	-5.49 (-9.78, -1.2)	MD 5.49 lower (9.78 to 1.2 lower)	Very low

(a) Unclear blinding. Limitations were considered by study weights in the meta-analysis
(b) Confidence interval crosses one end of default MID (0.5) for single studies and default 0.5 *median control SD for 2 or more studies.
(c) Unclear allocation concealment. Limitations were considered by study weights in the meta-analysis
(d) Unclear blinding and allocation concealment. Limitations were considered by study weights in the meta-analysis
(e) Confidence interval crosses MID (8.6)
(f) Confidence interval crosses MID (6.47)
(g) Mean difference did not reach agreed MID of 0.16m/sec for the walking speed between the intervention and control group
(h) Confidence interval crosses both ends of default MID (0.5)
(i) Mean difference did not reach the agreed MID of 10 secs. for the Time Up and Go between the intervention and control group
(j) Heterogeneity: I^2 = 78%
(k) Heterogeneity: I^2 = 57%

Comparison: Resistance training versus usual care

Table 95: Resistance training - end of retention follow-up versus usual care- Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Resistance training - end of retention follow-up Mean (SD)	Control Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) (95% CI)	
Physical fitness - muscle strength, knee extension (Nm) - After usual care (Better indicated by higher values)										
1 Flansbjer 2008 [84]	RCT- single blind	Serious limitation(c)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	59.4 (22.6)	42 (20.1)	17.4 (-0.01, 34.81)	MD 17.4 higher (0.01 lower to 34.81 higher)	Low
Physical fitness - muscle strength, knee flexion (Nm) - After usual care (Better indicated by higher values)										
1 Flansbjer 2008 [84]	RCT- single blind	Serious limitation(c)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	70.6 (26.7)	53 (22.1)	17.6 (-2.17, 37.37)	MD 17.6 higher (2.17 lower to 37.37 higher)	Low
Mobility - maximal gait speed (m/min) - After usual care (Better indicated by higher values)										
1 Flansbjer 2008 [84]	RCT- single blind	Serious limitation(c)	No serious inconsistency	No serious indirectness	No serious imprecision	96.6 (59.4)	116.4 (106.8)	-19.8 (-95.77, 56.17)	MD 19.8 lower (95.77 lower to 56.17 higher)	Moderate
Mobility - Rivermead (Better indicated by lower values)										
1	RCT- single	No serious	No serious	No serious	Very serious	39.9 (7.2)	39.7	0.2 (-	MD 0.2	Low

Quality assessment						Summary of findings				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Resistance training - end of retention follow-up Mean (SD)	Control Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) (95% CI)	
Cooke 2010 [47]	blind	limitation	inconsistency	indirectness	imprecision(d)		(5.7)	3.34, 3.74)	higher (3.34 lower to 3.74 higher)	
Physical function - Timed Up and Go (sec) - After usual care (Better indicated by lower values)										
1 Flansbjer 2008 [84]	RCT- single blind	Serious limitation(c)	No serious inconsistency	No serious indirectness	Serious imprecision	23.6 (11.1)	26.7 (18.9)	-3.1 (-16.67, 10.47)	MD 3.1 lower (16.67 lower to 10.47 higher)	Low
Mood - Centre for Epidemiologic Studies for Depression scale (CES-D) - After usual care (Better indicated by lower values)										
1 Sims 2009 [238]	RCT- single blind	Very serious limitation(a);(c)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	13.78 (8.02)	22.7 (11.17)	-8.92 (-13.03, -4.81)	MD 8.92 lower (13.03 to 4.81 lower)	Very low
EuroQol Self-perceived health (Better indicated by higher values)										
1 Cooke 2010 [47]	RCT- single blind	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision(b)	69.6 (19.3)	66.2 (18.9)	3.4 (-7.31, 14.11)	MD 3.4 higher (7.31 lower to 14.11 higher)	Moderate

(a) Unclear blinding.
(b) Confidence interval crosses one end of default MID (0.5)
(c) Unclear allocation concealment
(d) Confidence interval crosses both ends of default MID (0.5)

Comparison: Cardiorespiratory versus resistance training

Table 96: Cardiorespiratory versus resistance training- Clinical study characteristics and clinical summary of findings

Quality assessment						No of patients				
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Cardiorespiratory versus resistance training Mean (SD)	Usual care Mean (SD)	Effect		Confidence (in effect)
								Mean difference (95% CI)	Mean Difference (MD) (95% CI)	
Mobility - gait preferred speed (m/min) - Cardiorespiratory training (Better indicated by lower values)										
4 Cuviello-Palmer 1988 [52]; Katz-Leurer 2003 [134]; Moore 2010 [177]; Salbach 2004 [229]	RCT- single blind	Serious limitation(a)	No serious inconsistency	No serious indirectness	Serious imprecision(b)	Cuviello-Palmer: 18.11 (9.22) Katz-Leurer: 30.6 (10.8) Moore: 37.8 (18) Salbach: 46.8 (24)	Cuviello-Palmer: 12.07 (6.41) Katz-Leurer: 27 (9.6) Moore: 34.8 (13.8) Salbach: 38.4 (22.2)	4.68 (1.4, 7.96)	MD 4.68 higher (1.4 to 7.96 higher)	Low
Mobility - gait preferred speed (m/min) - Resistance training (Better indicated by lower values)										
3 Bale 2008 [14]; Kim 2001 [136]; Ouellette 2004 [195]	RCT- single and double blind	Serious limitation(c)	Very serious inconsistency(d)	No serious indirectness	Serious imprecision(b)	Bale: 13.8 (6) Kim: 2.4 (7.8) Ouellette: 38.4 (22)	Bale: 4.8 (6) Kim: 5.4 (4.2) Ouellette: 38.4 (24.75)	2.34 (-6.77, 11.45)	MD 2.34 higher (6.77 lower to 11.45 higher)	Very low

(a) Unclear blinding and unclear allocation concealment. Limitations were considered by study weights in the meta-analysis
(b) Mean difference did not reach agreed MID of 0.16m/sec for the walking speed between the intervention and control group

(c) Unclear allocation concealment
(d) Heterogeneity: $I^2 = 78\%$

13.2.1.2 Economic evidence

Literature review

No relevant economic evaluations were identified on cardiorespiratory or resistance fitness training.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

Cardiorespiratory training is delivered as part of usual rehabilitation programmes by physiotherapists. The cost per hour of a community based physiotherapist is £30.[51] The GDG acknowledged that additional costs would be incurred if people are referred for training programmes post-rehabilitation.

13.2.1.3 Evidence statements

Clinical evidence statements

End of intervention:

Functional independence measure

Three studies[19 52 134] of 162 participants found no significant difference in FIM –Disability between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

- One study[19]of 52 participants found no significant difference in FIM –Disability between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (MODERATE CONFIDENCE IN EFFECT)
- Two studies[52 134] of 110 participants found no significant difference in FIM –Disability between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

Rivermead Mobility Index

Four studies[19,125,267 94]of 488 participants found that cardiorespiratory training was associated with a significant improvement in the level of disability as measured by Rivermead Mobility Index, compared to usual care at the end of intervention (MODERATE CONFIDENCE IN EFFECT). Rivermead Mobility Index was then subdivided into groups of studies where participants in the control group still received usual care rehabilitation (during usual care) and those where participants were recruited who may not currently receive usual care rehabilitation (after usual care).

- During usual care: Three studies[19,125,267 94] comprising 452 participants found that cardiorespiratory training was associated with a significant improvement in the level of disability, as measured by the Rivermead Mobility Index, compared to usual care at the end of intervention (MODERATE CONFIDENCE IN EFFECT).
- After usual care: One study[94,94] of 36 participants found that cardiorespiratory training significantly improved level of disability as assessed with the Rivermead Mobility Index, compared to usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

Physical Activity and Disability scale

One study[180] of 58 participants found no significant difference in the Physical Activity and Disability scale between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

Systolic blood pressure

Four studies[53 134 152 211] of 190 participants found no significant difference in systolic blood pressure – Risk factors between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

- One study[53] of 12 participants found that usual care was associated with statistically significant improvement in systolic blood pressure –Risk factors compared to the cardiorespiratory training at the end of intervention (LOW CONFIDENCE IN EFFECT)
- Three studies[134 152 211] of 178 participants found no significant difference in systolic blood pressure –Risk factors between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (MODERATE CONFIDENCE IN EFFECT)

Diastolic blood pressure

Four studies[53 134 152 211] of 190 participants found no significant difference in diastolic blood pressure –Risk factors between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (MODERATE CONFIDENCE IN EFFECT)

- One study[53] of 12 participants found no significant difference in diastolic blood pressure – Risk factors between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)
- Three studies[134 152 211] of 178 participants found no significant difference in diastolic blood pressure –Risk factors between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (MODERATE CONFIDENCE IN EFFECT)

Peak VO2

Six studies[53 152 177 94,125,211] comprising 289 participants found a significant improvement in peak oxygen uptake (VO2) – Physical fitness in favour of the participants that received cardio-respiratory training compared to the participants that received usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

- Two studies [53,125] of 145 participants found a significant difference in peak oxygen uptake (VO2) – Physical fitness in favour of the participants that received cardio-respiratory training compared to the participants that received usual care at the end of intervention (MODERATE CONFIDENCE IN EFFECT)
- Four studies[152 177 94,211] of 144 participants found a significant improvement in peak oxygen uptake (VO2) – Physical fitness in favour of the participants that received cardio-respiratory training compared to the participants that received usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

Gait economy, VO2

One study[177]of 20 participants found no significant difference in Gait economy, VO2-Physical fitness between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

Maximum cycling work rate

Four studies[19 53 134 211] of 221 participants found that cardiorespiratory training was associated with a statistically significant difference in maximum cycling work rate-Physical fitness compared to usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

- Two studies[19 53] of 89 participants found no significant difference in maximum cycling work rate-Physical fitness between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (MODERATE CONFIDENCE IN EFFECT)
- Two studies[134 211] of 132 participants found that the cardiorespiratory training was associated with statistically significant improvement in maximum cycling work rate-Physical fitness compared to usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

Body mass (KG)

One study[19]of 72 participants found no significant difference in Body mass (KG) – Physical fitness between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (MODERATE CONFIDENCE IN EFFECT)

Functional Ambulation Categories

Two studies[53 208] of 73 participants found that cardiorespiratory training was associated with statistically significant improvement in Functional Ambulation Categories – Mobility compared to the usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

Maximal gait speed

Seven studies[53 208 19,74 229 177 180] of 365 participants found that cardiorespiratory training was associated with statistically significant improvement in maximal gait speed - Mobility compared to the usual care at the end of intervention, although this difference was not of clinical significance (MODERATE CONFIDENCE IN EFFECT)

- Four studies[53 208 19,74]of 196 participants found no significant difference in maximal gait speed - Mobility between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (MODERATE CONFIDENCE IN EFFECT)
- Three studies[229 177 180] of 169 participants found that cardiorespiratory training was associated with statistically significant improvement in maximal gait speed - Mobility compared to the usual care at the end of intervention. This difference was not clinically significant (LOW CONFIDENCE IN EFFECT)

Preferred gait speed

Four studies[52 134 177 229] of 221 participants found that cardiorespiratory training was associated with statistically significant improvement in preferred gait speed - Mobility compared to the usual care at the end of intervention. This difference was of clinical significance (MODERATE CONFIDENCE IN EFFECT)

- One study[52]of 20 participants found no significant difference in preferred gait speed - Mobility between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)
- Three studies[134 177 229] of 201 participants found that cardiorespiratory training was associated with statistically significant improvement in preferred gait speed - Mobility compared to the usual care at the end of intervention. This difference was of clinical significance (MODERATE CONFIDENCE IN EFFECT)

Gait endurance (6-MWT metres)

Seven studies[74 177 180 94,125,229,267]of 630 participants found that cardiorespiratory training was associated with statistically significant improvement in gait endurance (6-MWT metres) - Mobility compared to the usual care at the end of intervention. (VERY LOW CONFIDENCE IN EFFECT)

- Three studies[74,125,267]of 425 participants found no significant difference in gait endurance (6-MWT metres) - Mobility between the participants who received cardiorespiratory training

and those who received usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

- Four studies[177 180 229 94] of 205 participants found that cardiorespiratory training was associated with statistically significant improvement in gait endurance (6-MWT metres) - Mobility compared to the usual care at the end of intervention. This difference was not clinically significant (LOW CONFIDENCE IN EFFECT)

Maximal gait speed (m/sec over 10 meters)

One study [94] of 36 participants found that cardiorespiratory training was associated with statistically significant improvement in maximal gait speed – Mobility (m/sec over 10 meters) compared to the usual care at the end of intervention, although this difference was not of clinical significance (Low CONFIDENCE IN EFFECT)

Comfortable gait speed (m/sec over 5 to 10 meters)

Two studies[94,267]of 278 participants found that cardiorespiratory training was associated with statistically significant improvement in comfortable gait speed - Mobility compared to the usual care at the end of intervention. (LOW CONFIDENCE IN EFFECT)

- One study[267]of 242 participants found that cardiorespiratory training was associated with statistically significant improvement in comfortable gait speed - Mobility compared to the usual care at the end of intervention. (LOW CONFIDENCE IN EFFECT)
- One study[94] of 36 participants found cardiorespiratory training was not associated with statistically significant improvement in comfortable gait speed - Mobility compared to the usual care at the end of intervention. (LOW CONFIDENCE IN EFFECT)

Gait endurance (m/min)

Three studies[53 74 229] of 154 participants found that cardiorespiratory training was associated with statistically significant improvement in gait endurance (m/min) - Mobility compared to the usual care at the end of intervention, although this difference was not of clinical significance(LOW CONFIDENCE IN EFFECT)

- Two studies[53 74]of 63 participants found no significant difference in gait endurance (m/min) - Mobility between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (MODERATE CONFIDENCE IN EFFECT)
- One study[229] of 91 participants found no significant difference in gait endurance (m/min) - Mobility between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

6 metre walking time (sec)

One study[93]of 20 participants found no significant difference in 6 metre walking time (sec) - Mobility between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

Stroke Impact Scale

Two studies[244,267] of 262 participants found that cardiorespiratory training was associated with a statistically significant improvement in the impact of the stroke, as measured by the stroke impact scale – Mobility, compared to the usual care at the end of intervention. (MODERATE CONFIDENCE IN EFFECT)

- One study[267]of 242 participants found that cardiorespiratory training was associated with statistically significant improvement in the impact of the stroke, as measured by the stroke impact scale – Mobility, compared to the usual care at the end of intervention. (MODERATE CONFIDENCE IN EFFECT)

- One study[244]of 20 participants found no significant difference in Stroke Impact Scale (mobility domain) between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

Peak activity index (steps/min)

One study[180] of 58 participants found that cardiorespiratory training was associated with statistically significant improvement in Peak activity index (steps/min) – mobility compared to the usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

Maximum step rate

One study[180] of 58 participants found that cardiorespiratory training was associated with statistically significant improvement in Maximum step rate – mobility compared to the usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

Berg Balance scale

Five studies[19 229 94,177 125] of 357 participants found no significant difference in Berg Balance scale – Physical function between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

- During usual care: Two studies[19,125] of 210 participants found no significant difference in Berg Balance scale – Physical function between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (MODERATE CONFIDENCE IN EFFECT)
- After usual care: Three studies[229 94,177] of 147 participants found difference significant improvement in Berg Balance scale – Physical function associated with cardiorespiratory training compared to usual care. (LOW CONFIDENCE IN EFFECT)

Time Up and Go measure

Three studies [229 177,267] of 353 participants found that cardiorespiratory training significantly improved Timed Up and Go response – Physical function compared to usual care at the end of intervention. This improvement was not large enough to indicate clear clinical benefit (HIGH CONFIDENCE IN EFFECT).

- During usual care: One study [267]of 142 participants that cardiorespiratory training significantly improved Timed Up and Go response – Physical function compared to usual care at the end of intervention. This improvement was not large enough to indicate clear clinical benefit (HIGH CONFIDENCE IN EFFECT)
- Two studies[177 229] of 111 participants found no significant difference in the Time Up and Go measure – Physical function between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

Health related QoL

One study[3]of 28 participants found that cardiorespiratory training was associated with statistically significant improvement in Health related QoL (SF-36 - Emotional role functioning domain) compared to the usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

Three studies [3,94,113] of 97 participants found no significant difference in Health related QoL (SF-36 or SF-12 - Physical functioning domain) between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

One study[113]of 33 participants found no significant difference in Health related QoL (SF-36 - Emotional role functioning domain) between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

One study[113]of 33 participants found no significant difference in Health related QoL (SF-36 - Mental health domain) between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

One study[113]of 33 participants found no significant difference in Health related QoL (SF-36 - Physical Component scale) between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

One study[113]of 33 participants found no significant difference in Health related QoL (SF-36 - Mental Component scale) between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

Mood

One study[244]of 20 participants found no significant difference in Mood (Beck Depression Index) between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

Two studies [19,267] of 302 participants found that cardiorespiratory training was not associated with statistically significant improvement in anxiety (HADS – anxiety score) compared to the usual care at the end of intervention (MODERATE CONFIDENCE IN EFFECT)

Three studies[19,113,267] of 60 participants found no significant difference in depression (measured by HADS – depression score or the Geriatric Depression Scale) between the participants who received cardiorespiratory training and those who received usual care at the end of intervention (MODERATE CONFIDENCE IN EFFECT)

End of retention follow-up:

Case fatality

One study[134] of 81 participants found no significant difference in case fatality between the participants who received cardiorespiratory training and those who received usual care at the end of retention follow-up (VERY LOW CONFIDENCE IN EFFECT)

Rivermead Mobility Index

One study[19] of 66 participants found no significant difference in the Rivermead Mobility Index between the participants who received cardiorespiratory training and those who received usual care at the end of retention follow-up (MODERATE CONFIDENCE IN EFFECT)

Nottingham Extended ADL

One study[19] of 64 participants found no significant difference in the Nottingham Extended ADL between the participants who received cardiorespiratory training and those who received usual care at the end of retention follow-up (MODERATE CONFIDENCE IN EFFECT)

Physical Activity and Disability Scale

One study[180] of 58 participants found no significant difference in the Physical Activity and Disability Scale between the participants who received cardiorespiratory training and those who received usual care at the end of retention follow-up (LOW CONFIDENCE IN EFFECT)

Frenchay Activities Index

One study[134] of 79 participants found no significant difference in Frenchay Activities Index between the participants who received cardiorespiratory training and those who received usual care at the end of retention follow-up (LOW CONFIDENCE IN EFFECT)

Maximum cycling work rate

One study[19] of 66 participants found no significant difference in maximum cycling work rate between the participants who received cardiorespiratory training and those who received usual care at the end of retention follow-up (MODERATE CONFIDENCE IN EFFECT)

Body mass (Kg)

One study[19] of 64 participants found no significant difference in Body mass (Kg) between the participants who received cardiorespiratory training and those who received usual care at the end of retention follow-up (MODERATE CONFIDENCE IN EFFECT)

Maximal gait speed

Three studies[19,74 180] of 186 participants found that cardiorespiratory training was associated with statistically significant improvement in maximal gait speed - Mobility compared to the usual care at the end of retention follow-up, although this difference was not of clinical significance (MODERATE CONFIDENCE IN EFFECT)

- Two studies[19,74] of 128 participants found that cardiorespiratory training was associated with statistically significant improvement in maximal gait speed - Mobility compared to the usual care at the end of retention follow-up, although this difference was not of clinical significance (MODERATE CONFIDENCE IN EFFECT)
- One study[180] of 58 participants found that cardiorespiratory training was associated with statistically significant improvement in maximal gait speed - Mobility compared to the usual care at the end of retention follow-up, although this difference was not of clinical significance (LOW CONFIDENCE IN EFFECT)

6 Minute Walk Test

Two studies[74 180] of 107 participants found that cardiorespiratory training was associated with statistically significant improvement in 6 Minute Walk Test - Mobility compared to the usual care at the end of retention follow-up. This difference was of clinical significance (HIGH CONFIDENCE IN EFFECT)

- One study[74] of 49 participants found that cardiorespiratory training was associated with statistically significant improvement in 6 Minute Walk Test - Mobility compared to the usual care at the end of retention follow-up. This difference was not clinically significant (MODERATE CONFIDENCE IN EFFECT)
- One study[180] of 58 participants found that cardiorespiratory training was associated with statistically significant improvement in 6 Minute Walk Test - Mobility compared to the usual care at the end of retention follow-up. This difference was not clinically significant (LOW CONFIDENCE IN EFFECT)

Peak activity index (steps/min)

One study[180] of 58 participants found that cardiorespiratory training was associated with statistically significant improvement in peak activity index (steps/min) - Mobility compared to the usual care at the end of retention follow-up (LOW CONFIDENCE IN EFFECT)

Maximum step rate

One study[180] of 58 participants found that cardiorespiratory training was associated with statistically significant improvement in maximum step rate - Mobility compared to the usual care at the end of retention follow-up (LOW CONFIDENCE IN EFFECT)

Stroke Impact Scale

One study[244]of 20 participants found no significant difference in Stroke Impact Scale (mobility domain) between the participants who received cardiorespiratory training and those who received usual care at the end of retention follow-up (VERY LOW CONFIDENCE IN EFFECT)

Berg Balance scale

One study[19] of 66 participants found no significant difference in Berg Balance scale – Physical function between the participants who received cardiorespiratory training and those who received usual care at the end of retention follow-up (MODERATE CONFIDENCE IN EFFECT)

Mood

One study[244]of 20 participants found no significant difference in Mood (Beck Depression Index) between the participants who received cardiorespiratory training and those who received usual care at the end of retention follow-up (VERY LOW CONFIDENCE IN EFFECT)

One study[19] of 53 participants found no significant difference in Mood (HADS – anxiety score) between the participants who received cardiorespiratory training and those who received usual care at the end of retention follow-up (MODERATE CONFIDENCE IN EFFECT)

One study[19] of 53 participants found that cardiorespiratory training was associated with statistically significant improvement in Mood (HADS – depression score) compared to the usual care at the end of retention follow-up (MODERATE CONFIDENCE IN EFFECT)

One study[113]of 31 participants found no significant difference in Mood (Geriatric Depression Scale) between the participants who received cardiorespiratory training and those who received usual care at 6 months post-intervention (LOW CONFIDENCE IN EFFECT)

Health related QoL

One study[113]of 31 participants found no significant difference in Health related QoL (SF-36 - Physical Component scale) between the participants who received cardiorespiratory training and those who received usual care at 6 months post-intervention (VERY LOW CONFIDENCE IN EFFECT)

One study[113]of 31 participants found no significant difference in Health related QoL (SF-36 - Mental Component scale) between the participants who received cardiorespiratory training and those who received usual care at 6 months post-intervention (LOW CONFIDENCE IN EFFECT)

One study[113]of 31 participants found no significant difference in Health related QoL (SF-36 - Physical functioning domain) between the participants who received cardiorespiratory training and those who received usual care at 6 months post-intervention (VERY LOW CONFIDENCE IN EFFECT)

One study[113]of 31 participants found no significant difference in Health related QoL (SF-36 - Emotional role functioning domain) between the participants who received cardiorespiratory training and those who received usual care at 6 months post-intervention (LOW CONFIDENCE IN EFFECT)

One study[113]of 31 participants found no significant difference in Health related QoL (SF-36 - Mental health domain) between the participants who received cardiorespiratory training and those who received usual care at 6 months post-intervention (VERY LOW CONFIDENCE IN EFFECT)

Resistance training: End of intervention

Muscle strength

Two studies[285] [136] of 60 participants found that resistance training was associated with statistically significant improvement in composite measure of muscle strength compared to usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

- One study[285] of 40 participants found no significant difference in composite measure of muscle strength between the participants who received resistance training and those who received usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)
- One study[136] of 20 participants found no significant difference in composite measure of muscle strength between the participants who received resistance training and those who received usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

Knee extension (Nm)

Two studies [14] [84] of 42 participants found no significant difference in knee extension (Nm) between the participants who received resistance training and those who received usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

- One study [14] of 18 participants found no significant difference in knee extension (Nm) between the participants who received resistance training and those who received usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)
- One study [84] of 24 participants found that resistance training was associated with statistically significant improvement in knee extension (Nm) compared to usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

Knee flexion (Nm)

Two studies [14] [84] of 42 participants found no significant difference in knee flexion (Nm) between the participants who received resistance training and those who received usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

- One study [14] of 18 participants found no significant difference in knee flexion (Nm) between the participants who received resistance training and those who received usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)
- One study [84] of 24 participants found that resistance training was associated with statistically significant improvement in knee flexion (Nm) compared to usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

Maximal gait speed

Two studies [14] [84] of 42 participants found no significant difference in maximal gait speed between the participants who received resistance training and those who received usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

- One study [14] of 18 participants found that resistance training was associated with statistically significant improvement in maximal gait speed compared to usual care at the end of intervention, although this difference was not of clinical significance (VERY LOW CONFIDENCE IN EFFECT)
- One study [84] of 24 participants found no significant difference in maximal gait speed between the participants who received resistance training and those who received usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

Preferred gait speed

One study [14] of 18 participants found that resistance training was associated with statistically significant improvement in preferred gait speed compared to usual care at the end of intervention, although this difference was not of clinical significance (VERY LOW CONFIDENCE IN EFFECT)

Rivermead Mobility Index

One study [47]of 68 participants found no significant difference in Rivermead Mobility Index between the participants who received resistance training and those who received usual care at the end of intervention (MODERATE CONFIDENCE IN EFFECT)

Weight bearing (affected side)

One study [14] of 18 participants found that resistance training was associated with statistically significant improvement in weight bearing (affected side) compared to usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

Stair climbing

Two studies [136] [195]of 61 participants found no significant difference in stair climbing between the participants who received resistance training and those who received usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

Timed Up and Go (sec)

One study [84] of 24 participants found no significant difference in Timed Up and Go (sec) between the participants who received resistance training and those who received usual care at the end of intervention (LOW CONFIDENCE IN EFFECT)

Health related QoL

One study [136] of 20 participants found no significant difference in Health related QoL (SF-36 - Physical functioning domain) between the participants who received resistance training and those who received usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

One study [136] of 20 participants found no significant difference in Health related QoL (SF-36 – Mental health domain) between the participants who received resistance training and those who received usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

EuroQoL

One study [47]of 67 participants found no significant difference in EuroQoL (Self-perceived health) between the participants who received resistance training and those who received usual care at the end of intervention (MODERATE CONFIDENCE IN EFFECT)

Mood

One study [238]of 88 participants found that resistance training was associated with statistically significant improvement in Mood (Centre for Epidemiology Studies for Depression scale) compared to usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

End of retention follow-up:

Knee extension (Nm)

One study [84] of 24 participants found no significant difference in knee extension (Nm) between the participants who received resistance training and those who received usual care at the end of retention follow-up (LOW CONFIDENCE IN EFFECT)

Knee flexion (Newton metre)

One study [84] of 24 participants found no significant difference in knee flexion (Nm) between the participants who received resistance training and those who received usual care at the end of retention follow-up (LOW CONFIDENCE IN EFFECT)

Maximal gait speed

One study [84] of 24 participants found no significant difference in maximal gait speed between the participants who received resistance training and those who received usual care at the end of retention follow-up (MODERATE CONFIDENCE IN EFFECT)

Rivermead Mobility Index

One study [47]of 51 participants found no significant difference in Rivermead Mobility Index between the participants who received resistance training and those who received usual care at the end of retention follow-up (LOW CONFIDENCE IN EFFECT)

Timed Up and Go (sec)

One study [84] of 24 participants found no significant difference in Timed Up and Go (sec) between the participants who received resistance training and those who received usual care at the end of retention follow-up (LOW CONFIDENCE IN EFFECT)

Mood

One study [238] of 86 participants found that resistance training was associated with statistically significant improvement in Mood (Centre for Epidemiology Studies for Depression scale) compared to usual care at the end of retention follow-up (VERY LOW CONFIDENCE IN EFFECT)

EuroQoL

One study [47]of 49 participants found no significant difference in EuroQoL (Self-perceived health) between the participants who received resistance training and those who received usual care at the end of retention follow-up (MODERATE CONFIDENCE IN EFFECT)

Cardiorespiratory versus Resistance training:

Preferred gait speed

Four studies[52 134 177 229] of 221 participants found that cardiorespiratory training was associated with statistically significant improvement in preferred gait speed - Mobility compared to the usual care, although this difference was not of clinical significance (LOW CONFIDENCE IN EFFECT)

Three studies [14 136 195]of 80 participants found no significant difference in preferred gait speed - Mobility between the participants who received resistance training and those who received usual care at the end of intervention (VERY LOW CONFIDENCE IN EFFECT)

Economic evidence statement

No cost-effectiveness evidence was identified.

13.2.2 Recommendations and links to evidence

	81. Encourage people to participate in physical activity after stroke. **82. Assess people who are able to walk and are medically stable after their stroke for cardiorespiratory and resistance training appropriate to their individual goals.**

	83. Cardiorespiratory and resistance training for people with stroke should be started by a physiotherapist with the aim that the person continues the programme independently based on the physiotherapist's instructions (see recommendation 84). **84. For people with stroke who are continuing an exercise programme independently, physiotherapists should supply any necessary information about interventions and adaptations so that where the person is using an exercise provider, the provider can ensure their programme is safe and tailored to their needs and goals. This information may take the form of written instructions, telephone conversations or a joint visit with the provider and the person with stroke, depending on the needs and abilities of the exercise provider and the person with stroke.** **85. Tell people who are participating in fitness activities after stroke about common potential problems, such as shoulder pain, and advise them to seek advice from their GP or therapist if these occur.**
Relative values of different outcomes	The GDG agreed that being fit has an impact on: cardiovascular mortality, obesity, speed, endurance and mood. The GDG considered those outcomes measuring fitness, mobility and mood to be important.
Trade-off between clinical benefits and harms	There is a general agreement that physical activity is beneficial. The Cochrane review demonstrated improvements in physical fitness, mobility and mood and that respiratory training improved speed, tolerance and independence in walking. The GDG noted that all people included within the studies had some walking capacity at baseline. The studies did not comment on harm or potential side-effects. Adverse events were not consistently reported within these studies but require serious consideration. The GDG agreed that people need to be cardiovascularly stable (their treatment is not changing and their symptoms are not getting worse), but having symptoms does not mean that they cannot exercise. The GDG agreed that cardiovascular exercise was safe under supervision for certain people. It was agreed that an assessment should be undertaken by a health professional to establish suitability for this type of intervention but that the benefits of exercise in preventing further deterioration were established. The group agreed that most fitness training is done in the community and as out-patients, and there are now programmes available of adapted fitness programmes suitable for a stroke population that would be safe. Ideally people would start their exercise programme under supervision of a community physiotherapist and then a personal trainer who had knowledge and experience of working with people with disabilities who would continue the programme. Shoulder pain is the most likely harm people experience and therefore the GDG agreed that a recommendation to direct people to seek medical advice should be made.
Economic considerations	Cardiorespiratory training is delivered as part of usual rehabilitation programmes by physiotherapists. Fitness training is done in the community and the cost per hour of a community based physiotherapist is £30. The GDG acknowledged that additional costs would be incurred if people are referred for training programmes post-rehabilitation; the GDG felt that the potential costs of cardiorespiratory and fitness training are likely to be outweighed by the benefits.

Quality of evidence	The confidence in the effect of specified outcomes range from high to very low. Significant effects were found in the domains where such changes might be anticipated with cardiorespiratory and resistance interventions (i.e. physical fitness and mobility outcomes). These findings are consistent with results in other patient groups for similar fitness intervention studies. In the groups who received cardiorespiratory training significant improvements were found for gait speed, gait endurance and measures of physical fitness at the 'end of intervention' (time-point when a training programme finishes) and were retained at the 'end of follow-up' (any time-point occurring after the end of the intervention). Two recent large scale studies[125,267] contributed to many mobility outcomes and resulted in larger improvements of high to low quality for these outcomes. This also includes measures of stroke impact the evidence of which was rated as moderate quality.
Other considerations	The group felt that participating in exercise should generally be encouraged. The GDG also noted that the findings of the review were uncontroversial in that they highlight mobility and fitness as the main health gains. There was a discussion about medical suitability and the role of medical advice with regards to cardiorespiratory/resistance training. It was felt that there could potentially be serious medical risks associated with fitness training since many people who have had a stroke also have cardiac conditions. Since there would be a trade-off between benefits and potential harms, clinicians should assess and discuss these with people who have had a stroke who are considering taking part in such activities. The GDG also debated the issue of individual preference and personal history. Whether a person wants to take part in exercise training could depend on previous activity levels and work / life commitments. The group acknowledged a distinction between the goals of those wanting to regain functional ability and those who want to commit to progressive cardio-respiratory exercise requiring significant time and effort. Whilst fitness training may not be suitable or wanted by everyone, it was agreed physical activity at whatever level should be offered and promoted. The GDG highlighted the 'Start active stay active' report promoting regular physical activity throughout a person's life [62].Although fitness training tends to be done more commonly in the community setting rather than in the acute setting, studies have been done safely in the acute setting.

13.3 Hand and arm therapies: orthoses for the upper limb

Hand orthoses, or splints, are usually light-weight, formed supports for providing protection, rest, or alignment for the fingers, hand and wrist. After stroke, if hand function does not return, soft tissue tightness and contractures often occur leading to secondary problems of further limited function, pain, oedema and possibly, worsening spasticity. Hand splints are sometimes provided to aid in maintaining the length of soft tissues and thus the range of motion of the joints. They are also thought to reduce the effects of spasticity. However, there is differing opinion with regards to the design, schedules and clinical aims for upper limb splinting, as well as both biomechanical and neurophysiological clinical rationales. Additionally, there are respected members of the therapy professions who both support and contest the use of this clinical tool (Lannin NA, 2003 [145]).

13.3.1 Evidence review: In people after stroke what is the clinical and cost-effectiveness of orthoses for prevention of loss of range of movement in the upper limb versus usual care?

Clinical Methodological Introduction	
Population:	Adults and young people 16 or older who have had a stroke.
Intervention:	Orthoses for the upper limb including: • 'soft and scotch' casts, • splint, brace, low temperature splints, palm protector, lycra splinting

Clinical Methodological Introduction	
	• all the above interventions with or without botulinum toxin,
Comparison:	Usual Care
Outcomes:	Range of movement assessed by goniometry

13.3.1.1 Clinical evidence

Searches were conducted for systematic reviews and RCTs comparing the effectiveness of different types of orthoses as interventions for prevention of loss of range of movement in the upper limb for adults and young people over 16 years who had a previous stroke. Only studies with a minimum sample size of 20 participants (10 in each arm) were selected. Two RCTs[18,144] were identified. **Table 97** summarises the population, intervention, comparison and outcomes of the study.

Table 97: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix H.

Author Year	POPULATION	INTERVENTION	COMPARISON	OUTCOME
Lannin, 2007[144]	Adults who had a stroke within the previous 8 weeks and had no active wrist extension.	Two splinting interventions were studied. In both groups, custom made, static, palmar mitt splints for up to 12 hours overnight for 4 weeks were used. Neutral splint; participants wore a hand splint which positioned the wrist in 0^0 to 10^0 extension. (N=21) Extension splint: participants wore a hand splint, which positioned the wrist in a comfortable end-of-range position (>45^0 wrist extension) with the metacarpophalangeal and interphalangeal joints extended. (N=21)	Control group did not wear a hand splint for the study period. (N=21)	• Wrist extensibility (in degrees) at 4 and 6 weeks
Basaran 2012[18]	N=39 participants with a history of single stroke and wrist MAS score ≥1+; if taking antispasticity drugs, dosage had to be stable during previous month	Two splinting interventions were studied: static dorsal splint worn for up to 10 hours overnight for 5 weeks or static volar splint worn for up to 10 hours overnight for 5 weeks	All patients had home exercise program including motor training and stretching, reaching and grasping 3 times a day and advised to use hands as much as possible during the day for 5 weeks	• Passive range of motion (PROM) of wrist extension (goniometer)

Comparison: Neutral splint versus usual care

Table 98: Neutral splint versus usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Neutral splint Mean (sd)	Usual care Mean (sd)	Mean difference (95% ci)	Mean Difference (MD) (95% CI)	Confidence (in effect)
Wrist extensibility (in degrees) (4 weeks follow-up) (Better indicated by higher values)										
Lannin et al, 2007[144]	RCT	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision (b)	53.1 (14.9)	47.3 (16.9)	-1.40 (-8.20, 5.40)	MD 1.4 lower (8.2 lower to 5.4 higher)	Moderate
Wrist extensibility (in degrees) (6 weeks follow-up) (Better indicated by higher values)										
Lannin et al, 2007[144]	RCT	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision (b)	48.8 (14.5)	39.4 (17.8)	-4.20 (-11.65, 3.25)	MD 4.2 lower (11.65 lower to 3.25 higher)	Moderate

(a) Mean difference did not reach the agreed MID of 5^{O}.

Comparison: Extension splint versus usual care

Table 99: Extension splint versus usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Extension splint Mean (sd)	Usual care Mean (sd)	Mean difference (95% C I)	Mean Difference (MD) (95% CI)	Confidence (in effect)
Wrist extensibility (in degrees) (4 weeks follow-up) (Better indicated by higher values)										
Lannin et al, 2007[144]	RCT	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (b)	45.5 (15.4)	47.3 (16.9)	1.30 (-2.58, 5.18)	MD 1.3 higher (2.58 lower to 5.18 higher)	Moderate
Wrist extensibility (in degrees) (6 weeks follow-up) (Better indicated by higher values)										
Lannin et al, 2007[144]	RCT	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (b)	42.5 (14.9)	39.4 (17.8)	-0.80 (-5.05, 3.45)	MD 0.8 lower (5.05 lower to 3.45 higher)	Moderate

(a) Mean difference did not reach the agreed MID of 5^{O}.

Comparison: Dorsal / Volar splint versus usual care

Table 100: Dorsal / Volar splint versus usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of Findings				
						Static dorsal / volar splint Mean change from baseline (SD)	Usual care Mean change from baseline (SD)	Effect size		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision			Mean difference between intervention and control (95% CI)	Mean difference (95% CI)	Confidence in effect
Passive range of motion (PROM) of wrist extension - Dorsal splint (follow-up 5 weeks; measured with: mean change scores ; Better indicated by higher values)										
Basaran 2012	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious(a)	2.31 (8.07)	0.42 (4.5)	1.89 (-3.18, 6.96)	MD 1.89 higher (3.18 lower to 6.96 higher)	Low
Passive range of motion (PROM) of wrist extension - Volar splint (follow-up 5 weeks; measured with: Mean change scores; Better indicated by higher values)										
Basaran 2012	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious(b)	3.46 (7.18)	0.42 (4.5)	3.04 (-1.62, 7.70)	MD 3.04 higher (1.62 lower to 7.7 higher)	Moderate

[a]The confidence interval reaches from appreciable harm to appreciable benefit of the intervention (i.e. crosses both default MIDs)
[b]The confidence interval ranges from appreciable benefit to no effect (crosses one default MID)

13.3.1.2 Economic evidence

Literature review

No relevant economic evaluations comparing orthoses for prevention of loss of range of the upper limb with usual care were identified.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

The cost of providing wrist/hand orthoses was based on the RCT included in clinical review. In Lannin et al (2007)[144], they used custom-made static, palmar mitt splints. An expert advisor to the GDG provided the cost for a pre-fabricated splint: Resting pan position splint, £33.93 excluding VAT, though costs will vary according to type and design of prefabricated splint.

Custom-made orthoses would be made by a member of specialist multidisciplinary orthotics team and would incur extra costs. In addition, there would be personnel costs related to the time required to make and adjust the ULO to take into account the specific patient's needs. Adjustments may be made by either orthotists and experienced physiotherapists or occupational therapists (band 6 or 7), depending on the requirements (for example orthotists tend to make permanent and more complex adjustments). The estimated costs range from £45 to £59 per hour of client contact[r].

13.3.1.3 Evidence statements

Clinical evidence statements

Neutral splint

One study[144]comprising 42 participants found no significant difference on the wrist extensibility at 4 and 6 weeks follow-up for participants wearing neutral splint for 4 weeks compared to participants who received usual care. (MODERATE CONFIDENCE IN EFFECT)

Extension splint

One study[144]comprising 42 participants found no significant difference on the wrist extensibility at 4 and 6 weeks follow-up for participants wearing extension splint for 4 weeks compared to participants who received usual care. (MODERATE CONFIDENCE IN EFFECT)

Dorsal splint

One study [18] comprising 26 participants found no significant difference on the passive range of motion (PROM) of wrist extension after 5 weeks of intervention for participants wearing a static dorsal splint compared to participants who received usual care. (LOW CONFIDENCE IN EFFECT)

Volar splint

r Estimated based on data and methods from Personal Social Services Research Unit 'Unit costs of health and social care' report and Agenda for Change salary band 6 and 7[51] (typical salary band identified by clinical GDG members). Assumed that an orthotist is costed similar to a physiotherapist.

One study[18] comprising 26 participants found no significant difference on the passive range of motion (PROM) of wrist extension after 5 weeks of intervention for participants wearing a static volar splint compared to participants who received usual care. (MODERATE CONFIDENCE IN EFFECT)

Economic evidence statements

No cost effectiveness evidence was identified.

13.3.2 Recommendations and link to evidence

Recommendations:	**86. Do not routinely offer wrist and hand splints to people with upper limb weakness after stroke.** **87. Consider wrist and hand splints in people at risk after stroke (for example, people who have immobile hands due to weakness, and people with high tone), to:** • **maintain joint range, soft tissue length and alignment** • **increase soft tissue length and passive range of movement** • **facilitate function (for example, a hand splint to assist grip or function)** • **aid care or hygiene (for example, by enabling access to the palm)** • **increase comfort (for example, using a sheepskin palm protector to keep fingernails away from the palm of the hand).** **88. Where wrist and hand splints are used in people after stroke, they should be assessed and fitted by appropriately trained healthcare professionals and a review plan should be established.** **89. Teach the person with stroke and their family or carer how to put the splint on and take it off, care for the splint and monitor for signs of redness and skin breakdown. Provide a point of contact for the person if concerned.**
Relative values of different outcomes	Wrist splints are used to ensure that range of movement is not lost following stroke. Should loss of range of movement occur this would have an impact on upper limb function should movement at the hand and wrist recover. For this reason the outcome of interest included in the review was range of movement. The GDG noted that range of movement is one of a number of potential outcomes which include function and amount of muscle tone
Trade-off between clinical benefits and harms	An assessment of the use of splints includes checking if it fits and is worn properly, and a review plan established. The GDG agreed that information and training for the patient and carers was important for them to ensure the splint was used correctly and to recognise any adverse effects that would need professional care and advice. Potential contraindications may include sensory impairment, spasticity, poor skin condition including inflammation, oedema, and poor vascular

	supply, each of which may contribute to skin break down after stroke. The GDG agreed it was essential that the splint is assessed, fitted and monitored by staff trained in this area.
Economic considerations	No cost effectiveness studies were identified for this question. The cost of a pre-fabricated splint was estimated at around £34 excluding VAT though costs vary considerably. In addition, there is some personnel time required to assess and make adjustments for the patient as well as to ensure its correct use. Custom-made orthoses would be made by a member of specialist multidisciplinary orthotics team and would incur extra costs. In addition, there would be personnel costs related to the time required to make and adjust the ULO to take into account the specific patient's needs. Based on the results of the clinical review, the GDG did not consider wrist and hand splinting to be cost-effective as a routine treatment in the majority of patients.
Quality of evidence	Only two small studies, one in early post-acute stroke and one in later stroke rehabilitation were identified [18,144]. Confidence in the results seen in the wrist extensibility outcome was moderate to low due to not reaching the minimal important difference of 5 degrees as previously agreed with the GDG (see the method chapter) or the default MID. However the GDG considered both of these studies to be a robust rehabilitation studies and acknowledged the difficulties of double blinding in this type of intervention.
Other considerations	The GDG consensus was that routine splinting early after stroke would probably not be of benefit, except in selected patients where splinting may be used to help manage tone, reduce pain and improve function. Whether or not to use splints later on in the rehabilitation pathways was seen as unclear since the results can be interpreted as being inconclusive. Further research is needed to assess whether upper limb splinting in conjunction with other modalities aids the management of spasticity. To date, the details are not known as to whether upper limb splinting is useful in reducing problems in the poorly functioning hand after stroke either as a single intervention or in combination with other interventions such as botulinum toxin injections or electrical stimulation.

13.4 Electrical stimulation: upper limb

Functional electrical stimulation (FES) and neuromuscular electrical stimulation (NMES), used here to indicate a generic form of therapeutic electrical stimulation (ES) to muscles, are an adjunct to a comprehensive rehabilitation program to improve arm and hand function after stroke. It may be used for therapeutic purposes or for functional purposes. ES is seldom used in isolation, but most recently in tandem with or in addition to an active task oriented, exercise program. ES, applied usually via surface electrodes, but also occasionally through implanted electrodes, activates muscle contraction peripherally usually through stimulating nerves to muscles. With current technology, ES devices are small and easy to use and can be pre-programmed to prescribed cycles and duration, include multiple muscle groups, be passively or actively triggered and be used in some functional activities. Once set up by the appropriate health professional, the treatment can often be continued at home, enhancing the practice effect.

13.4.1 Evidence review: In people after stroke what is the clinical and cost-effectiveness of electrical stimulation (ES) for hand function versus usual care?

Clinical Methodological Introduction	

Clinical Methodological Introduction	
Population	Adults and young people 16 or older who have had a stroke
Intervention	Functional Electrical Stimulation (FES) with or without robotics, ES with or without transcranial magnetic stimulation or neuromuscular electrical stimulation (NMS)
Comparison	Usual care
Outcomes	Any outcome reported in the paper. Upper Limb outcomes including: • Action Research Arm Test (ARAT), • Fugl-Meyer Assessment (FMA), • 9 hole peg test, • grip strength.

13.4.1.1 Clinical evidence

Searches were conducted for systematic reviews and RCTs comparing the effectiveness of electrical stimulation (ES) to improve hand function for patients over 16 years old with stroke. Eighteen (18) RCTs were identified. **Table 101** summarises the population, intervention, comparison and outcomes for each of the studies.

Table 101: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix H.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Alon, 2007[6]	Patients with unilateral acute stroke (2-4 weeks ago) who were medically stable with a paresis of upper limb (Fugl-Meyer score 11-40) without limited range of passive motion and at least 60% finger flexion/ extension with stimulation.	FES plus standard rehabilitation training (usual care); electrical stimulation and induced contraction of wrist/finger extensors. FES was provided initially for 10 min/ 4 times daily in 2 sessions as part of their standard exercise and 2 sessions as not; the duration increased by 5 min/ day to 1 hour per session 4 times daily (FES was synchronised with exercise for 2 sessions, each lasted 30 min and the rest of FES training was not synchronized). (N=7)	Usual care; standard rehabilitation exercise (duration 3 hours) included physical, occupational (30 min twice daily 5 days a week during hospitalisation) and speech therapy within 1-2 days of admission. After discharge, patients practised 30 min twice daily unsupervised rehabilitation exercise for 1-2 visits per week. (N=8)	• Box and Blocks test • Jebsen-Taylor Hand Function test (light cans) • Modified Fugl-Meyer Assessment
Alon, 2008[7]	Patients with unilateral acute stroke (2-4 weeks ago) who were medically stable with	FES plus individually tailored exercise regimen (usual care). FES duration was increased by 5 min/	Usual care: individually tailored exercise regimen for 30 min sessions twice daily for 5 days/week	• Box and Blocks test, • Jebsen-Taylor Hand Function test (light cans),

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
	a paralysis/paresis of upper limb (Fugl-Meyer score 2-10) no limited range of passive motion; at least 60% finger flexion/extension with stimulation	day to 1 hour practiced for 4 times/ day. (N=13)	during hospitalisation; after discharge, usual care was provided for 30 min twice daily without supervision (occupation therapists/physiotherapists were involved in 1-2 sessions per week). (N=13)	• Modified Fugl-Meyer Assessment
Cauraugh, 2000[38]	Patients with chronic stroke (longer than a year ago) with chronic upper extremity impairment (upper limit cut-off of 75% motor recovery and for lower limit cut off point); subjects had to be capable of voluntarily extending the wrist 20° against gravity from a 90° flexion position.	Electromyography-triggered Neuromuscular Stimulation (EMG): subjects were instructed to initiate finger/wrist extension so that a target threshold of EMG activity was voluntarily achieved; EMG was provided in 2 sessions of 30 movement trials (around 60 min) during 3 days a week for 2 weeks. (N=7)	Usual care: patients followed the same procedure as the experimental group except that they did not receive the neuromuscular electrical stimulation. (N=4)	• Box and Blocks test • Motor Assessment Scale • Fugl-Meyer Assessment • 2 force-generation tasks
Cauraugh, 2002[39]	Patients with at least one cerebrovascular accident (CVA) and no more than 2 CVAs on the same side of the brain (upper limit cut-off of 80% motor recovery; for lower limit cut off point; subjects had to be capable of voluntarily extending the fingers/wrist 10° against gravity from a 90° flexion position.	Unilateral training group: EMG-triggered stimulation to assist wrist and finger extension (unilateral movement). (N=10) Bilateral training group: EMG-triggered stimulation plus assistance from unimpaired limb as wrist/finger extension executed simultaneously on both limbs (bilateral movement). 3 sets of 30 successful EMG-triggered trials (around 1.5 hours); total of 6 hours of training on 4 days during 2 weeks. (N=10)	Usual care: subjects tried to voluntarily extend wrist/fingers for 5 seconds followed by 25 seconds rest, repeatedly for 90 min. per session. (N=5)	• Box and Blocks test • Sustained muscle contraction
Chae, 1998 [41]	Stroke survivors admitted to an acute	15 sessions of stimulating the	15 sessions of surface stimulation, but the	• Fugl-Meyer Upper extremity

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
	inpatient rehabilitation service within 4 weeks of their unilateral stroke. Patients were 18yrs old or older with moderate to severe upper extremity paresis (Fugl-Meyer score less than 44), with no history of potentially fatal cardiac arrhythmias.	extensor digitorum communis and the extensor carpi radialis (ECR) through circular 2.5-cm surface electrodes in addition to standard physical, occupational, and speech therapy interventions. The stimulation current intensity was set to produce full wrist and finger extension with a duty cycle of 10 seconds on and 10 seconds off. (N=14)	electrodes were placed away from all motor points, producing only cutaneous stimulation just beyond sensory threshold and without motor activation in addition to standard physical, occupational, and speech therapy interventions. (N=14)	assessment • Functional Independence Measure
Chan, 2009[42]	Patients with first time stroke longer than 6 weeks ago with a score of 0 on finger mass extension sub-item of Fugl-Meyer Assessment.	FES with muscle movement (20 min) plus 10 min stretching/passive mobilization activities to facilitate active movement plus 60 min conventional occupational therapy training. Each FES session lasted 20 min, with 2 training activities out of 4 tasks. (N=10)	Usual care: stretching/passive mobilization activities to facilitate active movement (10 min) plus placebo electrical stimulation with sensation only (20 min) plus conventional occupational therapy training (60 min). (N=10)	• Functional Test for the Hemiplegic Upper Extremity, • Fugl-Meyer Upper extremity assessment • Grip Power • Active Range of Motion wrist extension • Functional Independence Measure • Modified Ashworth Scale of shoulder, elbow, wrist • Forward reaching distance
Hara, 2008[105]	Patients with chronic stroke (1 or 2 strokes on same side of brain longer than a year ago) and chronic spastic upper extremity impairments (Stroke Impairment Assessment Set [SIAS] scores 0-5) with passive range of motion in wrist extension to 45° from neutral and shoulder	FES for wrist extension during coordinated movement (triggered by voluntary movement by patient) for 30 minute/session for 5 days a week at home. FES training increased over 10 days to a maximum of 1 hour per session. Supervision was provided by an occupational	Supervision by a rehabilitation trainer in extending the impaired wrists and fingers during rehabilitation sessions once a week for about 5 months. Each session lasted approximately 40 min. (N=10)	• Active Range Of Movement (ROM) • electromyographic measures (maximum isometric contraction) • modified Ashworth scale (MAS) • 9 hole peg test

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
	flexion to 140°.	therapist for 40 min once a week for 5 months. (N=10)		
Hsu, 2010 [117]	Acute stroke patients with unilateral stroke, onset within 3 months, Brunnstrom stage ≤IV with no contraindication for NMES. Patients were randomised to 3 groups: high Neuromuscular Electrical Stimulation (NMES), low NMES, or control. (N=22)	4 weeks of NMES, 5 times per week in addition to regular inpatient rehabilitation. 30 minutes per session was chosen as the low dose NMES and 60 minutes as the high dose NMES. (N=22)	Regular inpatient rehabilitation	• Fugl-Meyer Upper extremity assessment • Action Research Arm Test • Motor Activity Log
Kimberley, 2004[137]	Patients with chronic stroke (longer than 6 months ago) experiencing at least 10° active flexion/extension at metacarpophalangeal joint of index finger; Mini-Mental State Examination score 25 or more out of possible 30.	Intensive home use of FES: 60 hours total use; 6 hours per day for 10 days over 3 weeks; half of the time using active effort by subject to trigger stimulated response then FES contracting muscles; other half machine automatically stimulating muscles to contract cyclically without trigger from patient. (N=8)	Sham treatment; light came on but no delivered by machine. (N=8)	• Box and Blocks test • Motor Activity Log: amount of use score (AS), how well scored (HW) • Jebsen Taylor Hand Function Test: page turn, small objects, feeding, stacking, light cans, heavy cans (all measured in sec). • Strength of finger extension, • Finger tracking accuracy test
Mangold, 2009[167]	First time stroke patients (2-18 weeks ago) with severe hemiparesis to total hemiplegia of arm and/or hand (maximum value of Chedoke McMaster Stroke Assessment [CMSA] for arm and hand 3 points).	FES lasted 45 min/session including 15-20 min of putting on and taking off FES / treating spasticity and 25-30 min of functional training and was offered in 3 sessions/week If necessary, therapists treated spasticity and provided manual assistance. FES triggered by patient or therapist.(N=12)	Conventional training provided for 3-5 occupational therapy sessions per week; each session lasted 45 min. Mobilisation and exercises supported by therapist or performed bimanually) (N=11).	• Nottingham Activities of daily Living • Chedoke McMaster Stroke Assessment (arm, hand) • Modified Ashworth Scale (finger flexors, wrist flexors)
Mann, 2005[168]	First time stroke patients (1-12	FES: stimulation to give full elbow, wrist	Passive extension exercises of elbow,	• Action Research Arm Test

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
	months post stroke) with hemiplegia (medically stable) and able to take hemiplegic hand to mouth.	and finger extension without discomfort; increased from 10 to 30 min twice a day over around 1 week. (N=11)	wrist and fingers to be practised for the same period each day. On discharge, continued with help of caregiver or independently. (N=11)	
Popovic, 2003[210]	First time stroke patients (2 weeks- 6 months post stroke) able to understand how to apply FES to control grasp. Patients were grouped to either higher functioning group (able to actively extend the paretic wrist more than 20° and extend their metacarpophalangeal and interphalangeal joints of all digits more than 20°) or to the lower functioning group (patients could extend the paretic wrist between 10° - 20°).	FES included reaching, grasping and using objects and returning them to their places during the first 3 weeks. FES exercise included 30 min long treatment sessions of exercise with stimulation for 7 days/ week. High functioning FES: (N=8) Low functioning FES: (N=6)	Usual care: conventional daily therapy for 26 weeks. For the first 3 weeks, control group had 30-min long treatment sessions of exercise only. High functioning usual care: (N=8) Low functioning usual care: (N=6)	• Upper Extremity Function Test (UEFT) • Drawing Test (% of area of square correctly captured) • Modified Ashworth scale • Reduced Upper Extremity Motor Activity Log questionnaire (RUE/MAL); maximum score, how well scale was
Powell, 1999[212]	Acute stroke patients (2-4 weeks after stroke) with Medical Research Council power of wrist extension grade 4/5 or worse at.	FES plus standard physiotherapy: 3 half-hour periods daily (total 90 mins. daily) for 8 weeks. (N=30)	Usual care: standard physiotherapy including discussing progress in rehabilitation up to 10 min for 3 times weekly to control for similar contact before and after FES sessions. (N=30)	• Grip strength • active and passive range of motion • Ashworth Scale • Action Research Arm Test • Number of pegs per second • Rankin scale • Barthel Index
Thrasher, 2008[257]	Hemiplegic patients hospitalised for recent stroke (2-7 weeks post stroke) with a score of 1 or 2 for combined arm and hand on Chedoke-McMaster Stages of Motor Recovery (CMSMR, i.e. spastic or flaccid paralysis of arm and	FES plus conventional occupational therapy and physiotherapy to shoulder, elbow, wrist and hand 5 days per week for 12-16 weeks; each session combined with FES for 45 mins. of the session; stimulator responded to push-button	Conventional occupational therapy and physiotherapy to shoulder, elbow, wrist and hand 5 days per week for 12-16 weeks; each session lasted 45 min (muscle facilitation, repetitive functional training, strengthening against	• Object manipulation • Palmar grip torque • Pinch grip pulling force • Barthel Index • Upper Extremity Fugl-Meyer Assessment • Upper Extremity

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
	hand with little or no voluntary movement).	command by therapist when patient tried unsuccessfully to perform task; therapist guided arm to ensure a normal movement. In early stages, all movements performed with FES; in later treatments FES used less. (N=10)	resistance, electrical stimulation for isolated muscle strengthening (not for functional training), activities of daily living including self-care and caregiver training. (N=11)	Chedoke-McMaster stages of Motion Recovery
Lin, 2011 [155]	First stroke patients (within 3 months post-onset) with hemiplegia of one upper limb and shoulder flexor strength before treatment was grade 3 or less (out of 5). Patients did not have severe cognitive dysfunction (they scored 7 or better on the abbreviated mental test).	Standard treatment plus Neuromuscular Electrical Stimulation (NES) lasting for 30 minutes, 5 days/week for 3 weeks. The 2-channel Respond Select II stimulator (Texas, USA) was used. (N=23)	Standard treatment, including physical therapy and occupational therapy, for 30 minutes on 5 days /week for 3 weeks. (N=23)	• Modified Ashworth Scale (MAS) • Upper limb section of the Fugl-Meyer Assessment (FMA-U) • Modified Barthel Index (MBI)
Sahin, 2012 [227]	Patients between 45-65 years of age, who had developed forearm flexor spasticity following a stroke. Hemiplegia was longer than one year; score 2 or 3 spasticity according to Modified Ashworth Scale (MAS) and a stable neurological state.	Neuromuscular Electrical Stimulation (NMES) and stretching with Proprioceptive Neuromuscular facilitation (PNF) applied to the upper extremity after hot treatment with infrared: 5 days a week for 20 sessions. (N=21)	Stretching with Proprioceptive Neuromuscular facilitation (PNF) applied to the upper extremity after hot treatment with infrared: 5 days a week for 20 sessions. (N=21)	• Wrist spasticity (MAS) • Wrist extension Range of Motion (degrees) • Brunnstrom motor scale (upper) • Functional Independence Measure (FIM) • Electrophysiological evaluation: Fmax/Mmax, Hmax/Mmax
Shindo 2011[237]	Participants with first time unilateral supratentorial stroke; stroke onset within 60 days; age 20-80 years; muscle activities in the affected extensor digitorum communis (EDC) detectable with surface electrodes; could not fully extend	3 weeks of Hybrid Assistive Neuromascular Dynamic Stimulation (HANDS) therapy: neuromuscular electrical stimulation with integrated volitional electrical stimulator (IVES) plus wrist splint for 8 hours a day plus	Wore the same wrist splint for 8 hours a day plus standard rehabilitation (1 hour physical therapy and 1 hour occupational therapy per day, 5 days a week plus speech therapy if indicated); instructed to use the affected hand as much as	• Fugl-Meyer Assessment (proximal and distal), • Action Research Arm Test, • Motor Activity Log Modified Ashworth Scale

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
	paretic fingers and could not extend paretic fingers individually; passive range of motion >0° for the affected wrist extension and -10° for metacarpophalangeal joint extension; Mini-Mental State Examination score >23	standard rehabilitation (1 hour physical therapy and 1 hour occupational therapy per day, 5 days a week plus speech therapy if indicated); instructed to use the affected hand as much as possible in activities of daily living (N=12)	possible in activities of daily living (N=12)	
Rosewilliam 2012[220]	Adult patients with a first stroke who had no arm function (score 0 in the Grasp subsection of the Action Research Arm Test) within 6 weeks of onset and no contraindications to surface neuromuscular electrical stimulation (sNMES).	sNMES for 6 weeks: electrical stimulators to wrist and finger extensors at least twice a day for 30-minute sessions for 5 days a week plus a defined module of upper limb physiotherapy for 6 weeks in addition to routine treatment on the stroke unit (N=45)	A defined module of upper limb physiotherapy for 6 weeks in addition to routine treatment on the stroke unit only (N=45)	• ARAT

Comparison: Electrical stimulation versus usual care

Table 102: Electrical stimulation versus usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
Box and Blocks (number of blocks moved in 1 minute) - Post-intervention (Better indicated by higher values) usual care										
2 Alon 2007[6], Alon 2008[7]	RCTs-unblinded	Very serious limitations(a)	No serious inconsistency	No serious indirectness	No serious imprecision	Alon 2007: 42.3 (16.6) Alon 2008: 10.5 (12)	Alon 2007: 26.3 (11) Alon 2008: 2.5 (4.9)	9.53 (3.20, 15.87)	MD 9.53 higher (3.2 to 15.87 higher)	Low
Box and Blocks (number of blocks moved in 1 minute) - Post-intervention (Better indicated by higher values) sham intervention										
1 Kimberley 2004[137]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	27 (4.8)	24.3 (6.1)	2.70 (-2.68, 8.08)	MD 2.70 (2.68 lower to 8.08 higher)	Low
Jebsen-Taylor Hand Function test (time to move 5 light cans) (post treatment effect) (Better indicated by lower values) usual care										
2 Alon 2007[6], Alon 2008[7]	RCTs-unblinded	Very serious limitations(a)	No serious inconsistency	No serious indirectness	No serious imprecision	Alon 2007: 6.7 (2.9) Alon 2008: 40.5 (22.8)	Alon 2007: 11.8 (5.4) Alon 2008: 52.9	-5.22 (-9.66, -0.78)	MD 5.22 lower (9.66 to 0.78 lower)	Low

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
							(17.3)			
Jebsen-Taylor Hand Function test (time to move five light cans) (post treatment effect) (Better indicated by lower values) sham intervention										
1 Kimberley 2004[137]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	10.8 (2.1)	34.9 (25.8)	-24.10 (-42.04, -6.16)	MD 24.10 lower (42.04 to 6.16 lower)	Moderate
Modified Fugl-Meyer Assessment (post treatment effect) (Better indicated by higher values)										
2 Alon 2007[6], Alon 2008[7]	RCTs-unblinded	Very serious limitations(a)	Serious inconsistency	Serious indirectness(n)	No serious imprecision	Alon 2007: 49 (5.1) Alon 2008: 24.2 (13.7)	Alon 2007: 40.6 (8.2) Alon 2008: 14.5 (10.3)	8.85 (3.35, 14.36)	MD 8.85 higher (3.35 to 14.36 higher)	Very low
Functional Test for the Hemiplegic Upper Extremity (post treatment effect) (Better indicated by higher values)										
1 Chan 2009[42]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	3.7 (0.5)	3.1 (0.6)	0.60 (0.12, 1.08)	MD 0.6 higher (0.12 to 1.08 higher)	Moderate
Forward reaching distance (cm) (post treatment effect) (Better indicated by higher values)										
1 Chan 2009[42]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	20.4 (9.8)	11.9 (12.4)	8.50 (-1.30, 18.30)	MD 8.5 higher (1.3 lower to 18.3 higher)	Low
Range of motion wrist extension (O) (post treatment effect) (Better indicated by higher values)										

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
2 Chan 2009[42], Sahin 2012 [227]	RCT- double blinded	No serious limitations	No serious inconsistency	No serious indirectness	No serious imprecision	Chan: 21 (28.5) Sahin: 25 (6.2)	Chan: 6.5 (18.9) Sahin: 23.8 (5.6)	1.57 (-1.96, 5.09)	MD 1.57 higher (1.96 lower to 5.09 higher)	⨁⨁⨁◯ LOW
Grip power (kg) (post treatment effect) (Better indicated by higher values)										
1 Chan 2009[42]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (f)	2.2 (2)	2.2 (2.1)	0.20 (-1.60, 2.00)	MD 0.2 higher (1.6 lower to 2 higher)	Low
Functional Independence Measure (FIM) (post intervention) (Better indicated by higher values)										
3 Chae 1998[41], Chan 2009[42], Sahin 2012 [227]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	Chae: 11.3 (3.0) Chan: 80.2 (6.8) Sahin: 109.8 (18.8)	Chae: 10.6 (5.9) Chan: 77.6 (12) Sahin: 102.7 (19.6)	1.40 (-1.69, 4.50)	MD 1.40 higher (1.69 lower to 4.50 higher)	Moderate
Functional Independence Measure (FIM) (4 weeks follow-up) (Better indicated by higher values)										
1 Chae 1998[41]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	13.9 (5.5)	13.6 (6.5)	0.30 (-4.16, 4.76)	MD 0.30 higher (4.16 lower to 4.76 higher)	Moderate
Functional Independence Measure (FIM) (12 weeks follow-up) (Better indicated by higher values)										
1 Chae	RCT- double	Serious	No serious	No serious	No serious	15.8 (5.8)	16.1 (6.7)	-0.30 (-	MD 0.30 lower	Modera

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
1998[41]	blinded	limitations(b)	inconsistency	indirectness	imprecision			4.94, 4.34)	(4.94 lower to 4.34 higher)	te
Modified Ashworth Scale of shoulder (post treatment effect) (Better indicated by lower values)										
1 Chan 2009[42]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	0.3 (0.5)	0.5 (0.6)	-0.20 (-0.68, 0.28)	MD 0.2 lower (0.68 lower to 0.28 higher)	Low
Modified Ashworth Scale elbow - Post-intervention (Better indicated by lower values)										
1 Chan 2009[42]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	1.3 (0.8)	1.6 (1.1)	-0.30 (-1.14, 0.54)	MD 0.30 lower (1.14 lower to 0.54 higher)	Low
Modified Ashworth Scale wrist - Post-intervention (Better indicated by lower values)										
1 Chan 2009[42]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	0.9 (0.9)	1.4 (1)	-0.50 (-1.33, 0.33)	MD 0.50 lower (1.33 lower to 0.33 higher)	Low
Strength of finger extension (Newtons) - Post-intervention (Better indicated by higher values)										
1 Kimberley 2004[137]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	12.9 (7.9)	8.9 (2.3)	4.00 (-1.70, 9.70)	MD 4 higher (1.7 lower to 9.7 higher)	Low
Motor Activity Log Amount of use score - Post-intervention (Better indicated by higher values)										
1 Kimberl	RCT- double blinded	Serious limitations(	No serious inconsistency	No serious indirectness	Serious imprecision (c)	1.9 (0.82)	1.3 (0.71)	0.60 (-0.15, 1.35)	MD 0.6 higher (0.15 lower to	Low

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
ey 2004[137]		b)							1.35 higher)	
Motor Activity Log How well used score - Post-intervention (Better indicated by higher values)										
1 Kimberley 2004[137]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	2.1 (0.84)	1.4 (0.73)	0.70 (-0.07, 1.47)	MD 0.7 higher (0.07 lower to 1.47 higher)	Low
Motor Activity Log: Amount of use: Low dose (Better indicated by higher values)										
1 Hsu, 2010 [117]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision	0.6 (1)	0.11 (0.29)	0.49 (0.05, 0.93)	MD 0.49 higher (0.05 to 0.93 higher)	Low
Motor Activity Log: Amount of use: High dose (Better indicated by higher values)										
1 Hsu, 2010 [117]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision	0.56 (0.87)	0.11 (0.29)	0.45 (0.07, 0.83)	MD 0.45 higher (0.07 to 0.83 higher)	Low
Motor Activity Log: Quality of movement: Low dose (Better indicated by higher values)										
1 Hsu, 2010 [117]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision	0.74 (1.22)	0.12 (0.32)	0.62 (0.09, 1.15)	MD 0.62 higher (0.09 to 1.15 higher)	Low
Motor Activity Log: Quality of movement: High dose (Better indicated by higher values)										
1 Hsu,	RCT- Single blinded	Serious limitations(	No serious inconsistency	No serious indirectness	Serious imprecision	0.69 (1.1)	0.12 (0.32)	0.57 (0.09, 1.05)	MD 0.57 higher (0.09 to 1.05	Low

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
2010 [117]		b)							higher)	
Jebsen-Taylor page turn test (s) - Post-intervention (Better indicated by lower values)										
1 Kimberley 2004[137]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	17.1 (5.7)	19.5 (4.3)	-2.40 (-7.35, 2.55)	MD 2.4 lower (7.35 lower to 2.55 higher)	Low
Jebsen-Taylor small objects test (s) - Post-intervention (Better indicated by lower values)										
1 Kimberley 2004[137]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	25 (5.3)	41.4 (12.6)	-16.40 (-25.87, -6.93)	MD 16.4 lower (6.93 to 25.87 lower)	Moderate
Jebsen-Taylor feeding test (s) - Post-intervention (Better indicated by lower values)										
1 Kimberley 2004[137]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	6.7 (2.52)	27.9 (6.9)	-21.20 (-26.29, -16.11)	MD 21.2 lower (16.11 to 26.29 lower)	Moderate
Jebsen-Taylor stacking test (s) - Post-intervention (Better indicated by lower values)										
1 Kimberley 2004[137]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	25.3 (7.6)	56.7 (26.6)	-31.40 (-50.57, -12.23)	MD 31.4 lower (12.23 to 50.57 lower)	Moderate
Jebsen-Taylor heavy cans test (s) - Post-intervention (Better indicated by lower values)										

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
1 Kimberley 2004[137]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Very serious imprecision (e)	42.4(35)	30.8 (21)	11.60 (-16.68, 39.88)	MD 11.6 higher (16.68 lower to 39.88 higher)	Very low
Finger tracking accuracy test (post treatment effect)										
1 Kimberley 2004[137]	RCT- double blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	-30 (2.1)	-6.2 (16)	-23.80 (-42.09, -5.51)	MD 23.80 lower (42.09 to 5.51 lower)	Low
Upper Extremity Function Test - Post-intervention high function group (Better indicated by higher values)										
1 Popovic 2003[210]	RCT-single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	18.8 (10.9)	9.6 (6.3)	9.2 (0.48, 17.92)	MD 9.2 higher (0.48 to 17.92 higher)	Moderate
Upper Extremity Function Test - Post-intervention low function group (Better indicated by higher values)										
1 Popovic 2003[210]	RCT-single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	1.9 (1.1)	0.2 (0.1)	1.7 (0.82, 2.58)	MD 1.7 higher (0.82 to 2.58 higher)	Moderate
Upper Extremity Function Test – Follow-up (26 weeks) high function group (Better indicated by higher values)										
1 Popovic 2003[210]	RCT-single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	29.9 (9.7)	15.4 (7.6)	14.5 (5.96, 23.04)	MD 14.5 higher (5.96 to 23.04 higher)	Moderate
Upper Extremity Function Test – Follow-up (26 weeks) low function group (Better indicated by higher values)										

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
1 Popovic 2003[210]	RCT-single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	4.9 (3.1)	1.5 (0.9)	3.4 (0.82, 5.98)	MD 3.4 higher (0.82 to 5.98 higher)	Moderate
Drawing ability (% area compared with target square) - Post-intervention high function group (range of scores: 0-100; Better indicated by higher values)										
1 Popovic 2003[210]	RCT-single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	83.8 (5.6)	68.7 (11.7)	15.10 (6.11, 24.09)	MD 15.1 higher (6.11 to 24.09 higher)	Low
Drawing test (% area compared with target square) (higher functioning group versus usual care) (26 weeks follow-up) (Better indicated by higher values)										
1 Popovic 2003[210]	RCT-single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	39.9 (8.1)	25.9 (8.6)	14.00 (5.81, 22.19)	MD 15.1 higher (6.11 to 24.09 higher)	Low
Drawing ability (% area compared with target square) - Post-intervention low function group (range of scores: 0-100; Better indicated by higher values)										
1 Popovic 2003[210]	RCT-single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	24 (9.9)	16 (2.8)	8.0 (-0.23, 16.23)	MD 8.0 higher (0.23 lower to 16.23 higher)	Low
Drawing ability (% area compared with target square) – Follow-up (26 weeks) high function group (follow-up mean 26 weeks; range of scores: 0-100; Better indicated by higher values)										
1 Popovic 2003[210]	RCT-single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (c	49.8 (9.6)	36.7 (6.9)	13.10 (3.64, 22.56)	MD 13.1 higher (3.64 to 22.56 higher)	Low
Modified Ashworth Scale (higher functioning group versus usual care) (26 weeks follow-up) (Better indicated by lower values)										
1	RCT-single	Serious	No serious	No serious	No serious	1.25 (0.5)	2.25	-1.00 (-	MD 1 lower	Modera

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
Popovic 2003[210]	blinded	limitations(b)	inconsistency	indirectness	imprecision		(0.75)	1.62, -0.38)	(0.38 to 1.62 lower)	te
Modified Ashworth Scale (lower functioning group versus usual care) (26 weeks follow-up) (Better indicated by lower values)										
1 Popovic 2003[210]	RCT-single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (f)	2.5 (0.75)	2.25 (0.75)	0.25 (-0.60, 1.10)	MD 0.25 higher (0.6 lower to 1.1 higher)	Low
Reduced Upper Extremity Motor Activity Log questionnaire- Amount scale (higher functioning group versus usual care) (26 weeks follow-up) (Better indicated by higher values)										
1 Popovic 2003[210]	RCT-single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	59.7 (2.5)	28.7 (11.7)	31.00 (19.14, 42.86)	MD 31 higher (19.14 to 42.86 higher)	Low
Reduced Upper Extremity Motor Activity Log questionnaire- Amount scale (lower functioning group versus usual care) (26 weeks follow-up) (Better indicated by higher values)										
1 Popovic 2003[210]	RCT-single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	16.7 (8.3)	3.3 (1.7)	13.40 (6.62, 20.18)	MD 13.40 higher (6.62 to 20.18 higher)	Low
Reduced Upper Extremity Motor Activity Log questionnaire- How well scale (higher functioning group versus usual care) (26 weeks follow-up) (Better indicated by higher values)										
1 Popovic	RCT-single blinded	Serious limitations(	No serious inconsistency	No serious indirectness	Serious imprecision (c)	66.7 (11.4)	32.5 (10.6)	34.20 (23.41,	MD 34.20	Low

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
2003[210]		b)						44.99)	higher (23.41 to 44.99 higher)	
Reduced Upper Extremity Motor Activity Log questionnaire- How well scale (lower functioning group versus usual care) (26 weeks follow-up) (Better indicated by higher values)										
1 Popovic 2003[210]	RCT-single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	11.5(6.1)	2.3 (1.2)	9.20 (4.23, 14.17)	MD 9.20 higher (4.23 to 14.17 higher)	Low
Change in Action Research Arm Test (total score) (4 weeks follow-up: Low dose FES) (Better indicated by higher values)										
1 Hsu, 2010 [117]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (h)	8.6 (11.3)	3.5 (8.2)	5.10 (-0.52, 10.72)	MD 5.1 higher (0.52 lower to 10.72 higher)	Low
Change in Action Research Arm Test (total score) (4 weeks follow-up: High dose FES) (Better indicated by higher values)										
1 Hsu, 2010 [117]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (h)	8.5 (13.2)	3.5 (8.2)	5.00 [-1.39, 11.39]	MD 5.0 higher (1.39 lower to 11.39	Low

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
									higher)	
Change in Action Research Arm Test (total score) (12 weeks follow-up: Low dose FES) (Better indicated by higher values)										
1 Hsu, 2010 [117]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (h)	17.2 (19.1)	4 (9.5)	13.20 (5.19, 21.21)	MD 5.1 higher (0.52 lower to 10.72 higher)	Low
Change in Action Research Arm Test (total score) (12 weeks follow-up) (Better indicated by higher values)										
2 Hsu, 2010 [117]; Mann 2005[168]	RCT	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision (h)	Hsu (high dose): 15.9 (18.4) Mann: 34.4	Hsu: 4 (9.5) Mann: 24.4	10.68 (5.68, 15.68)	MD 10 higher (3.77 to 16.23 higher)	Low
Change in Action Research Arm Test (total score) (24 weeks follow-up) (Better indicated by higher values)										
1 Mann 2005[168]	RCT	Very serious limitations(g)	No serious inconsistency	No serious indirectness	Serious imprecision (h)	34.4	24.7	9.70 (2.35, 17.05)	MD 9.70 higher (2.35 to 17.05 higher)	Very low
Activities of Daily Living (post treatment effect) (Better indicated by higher values)										
1 Mangold	RCT	Very serious limitations(	No serious inconsistency	No serious indirectness	(i)	3 (1, 3.3)	1.5 (0.8, 2)	P= 0.19(j)	(i)	Low(i)

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
2009[167]		g)								
Gain in Chedoke McMaster Stroke Assessment (arm) (post treatment effect) (Better indicated by higher values)										
1 Mangold 2009[167]	RCT	Very serious limitations(g)	No serious inconsistency	No serious indirectness	(i)	1 (0, 1)	0 (0,1)	P= 0.57(j)	(i)	Low(i)
Gain in Chedoke McMaster Stroke Assessment (hand) (post treatment effect) (Better indicated by higher values)										
1 Mangold 2009[167]	RCT	Very serious limitations(g)	No serious inconsistency	No serious indirectness	(i)	0 (0,1)	0.3 (0, 0.5)	P= 1.0(j)	(i)	Low (i)
Gain in Modified Ashworth Scale (finger flexors) (post treatment effect) (Better indicated by higher values)										
1 Mangold 2009[167]	RCT	Very serious limitations(g)	No serious inconsistency	No serious indirectness	(i)	0 (-0.5, 0.8)	0.5 (0, 1.1)	P= 0.17(j)	(i)	Low (i)
Gain in Modified Ashworth Scale (wrist flexors) (post treatment effect) (Better indicated by higher values)										
1 Mangold 2009[167]	RCT	Very serious limitations(g)	No serious inconsistency	No serious indirectness	(i)	0.5 (0, 1.3)	0.5 (0, 1.1)	P= 0.68 (j)	(i)	Low (i)
Change in grip strength (kg) (8 weeks follow-up) (Better indicated by higher values)										
1 Powell 1999[213]	RCT- single blinded	Serious limitations (k)	No serious inconsistency	No serious indirectness	(i)	2 (0, 3)	1 (0,4)	(i)	(i)	Moderate (i)
Change in grip strength (kg) (32 weeks follow-up) (Better indicated by higher values)										

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
1 Powell 1999[213]	RCT- single blinded	Serious limitations (k)	No serious inconsistency	No serious indirectness	(i)	2 (0, 8)	4 (0, 10)	(i)	(i)	Moderate (i)
Ashworth score (8 weeks follow-up) (Better indicated by higher values)										
1 Powell 1999[213]	RCT- single blinded	Serious limitations (k)	No serious inconsistency	No serious indirectness	(i)	0 (0, 1)	0 (0, 1)	(i)	(i)	Moderate (i)
Asworth score (32 weeks follow-up) (Better indicated by higher values)										
1 Powell 1999[213]	RCT- single blinded	Serious limitations (k)	No serious inconsistency	No serious indirectness	(i)	1 (0, 1.5)	1 (0, 1)	(i)	(i)	Moderate (i)
ARAT (total score) (8 weeks follow-up) (Better indicated by higher values)										
1 Powell 1999[213]	RCT- single blinded	Serious limitations (k)	No serious inconsistency	No serious indirectness	(i)	10 (0, 29)	2 (0, 14)	(i)	(i)	Moderate (i)
ARAT (total score) (32 weeks follow-up) (Better indicated by higher values)										
1 Powell 1999[213]	RCT- single blinded	Serious limitations (k)	No serious inconsistency	No serious indirectness	(i)	6 (0, 31)	1 (0, 16)	(i)	(i)	Moderate (i)
No of pegs per second (8 weeks follow-up) (Better indicated by higher values)										
1 Powell 1999[213]	RCT- single blinded	Serious limitations (k)	No serious inconsistency	No serious indirectness	(i)	0 (0, 13)	0 (0, 0.8)	(i)	(j)	Moderate (i)

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
No of pegs per second (32 weeks follow-up) (Better indicated by higher values)										
1 Powell 1999[213]	RCT- single blinded	Serious limitations (k)	No serious inconsistency	No serious indirectness	(i)	0 (0, 0.16)	0 (0, 0.11)	(i)	(i)	Moderate (i)
Barthel Index (8 weeks follow-up) (Better indicated by higher values)										
1 Powell 1999[213]	RCT- single blinded	Serious limitations (k)	No serious inconsistency	No serious indirectness	(i)	5 (3, 7)	4 (1, 6)	(i)	(i)	Moderate (i)
Barthel Index (8 weeks follow-up) (Better indicated by higher values)										
1 Powell 1999[213]	RCT- single blinded	Serious limitations (k)	No serious inconsistency	No serious indirectness	(i)	7 (5, 10)	4 (2, 9)	(i)	(i)	Moderate (i)
Rankin scale (8 weeks follow-up) (Better indicated by higher values)										
1 Powell 1999[213]	RCT- single blinded	Serious limitations (k)	No serious inconsistency	No serious indirectness	(i)	-1 (-1, 0)	-1 (-1, 0)	(i)	(i)	Moderate (i)
Rankin scale score (32 weeks follow-up) (Better indicated by higher values)										
1 Powell 1999[213]	RCT- single blinded	Serious limitations (k)	No serious inconsistency	No serious indirectness	(i)	-1 (-2, 0)	-1 (-1, 0)	(i)	(i)	Moderate (i)
Fugl-Meyer Assessment - Upper Limb (post treatment effect) (Better indicated by higher values)										
3	RCT- Single	Serious	No serious	No serious	No serious	Chae: 13.1	Chae:	5.72 (2.79,	MD 5.72	Moderate

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
Chae 1998[41], Chan 2009[42]; Lin, 2011 [155]	blinded	limitations(b)	inconsistency	indirectness	imprecision	(10.3) Chan: 25.9 (8.9) Lin: 20.3 (5.4)	6.5 (6.1) Chan: 22.1 (9.9) Lin: 14.5 (5.8)	8.65)	higher (2.79 to 8.65 higher)	
Fugl-Meyer Assessment - Upper Limb (total) (1 week follow-up) (Better indicated by higher values)										
4 Chae 1998[41];Chan 2009[42]; Lin, 2011 [155]; Shindo 20011[237]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	Chae: 13.1 (10.3) Chan: : 25.9 (8.9) Lin: 20.3 (5.4) Shindo: 12.2 (5.3)	Chae: 9.7 (7.7) Chan: 22.1 (9.9) Lin: 14.5 (5.8) Shindo: 5.5 (6)	5.98 (3.45, 8.50)	MD 5.98 higher (3.45 to 8.50 higher)	Moderate
Fugl-Meyer Assessment - Upper Limb (total) (12 weeks) (Better indicated by higher values)										
3 Chae 1998[41]; Hsu, 2010 [117]; Lin, 2011 [155]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	Chae: 17.8 (12.6) Hsu (high dose): 25.5 (20) Lin: 22.6	Chae: 9.7 (7.7) Hsu: 14.2 (14.5) Lin: 17.7	6.11 (2.85, 9.38)	MD 6.11 higher (2.85 to 9.38 higher)	Moderate

Quality assessment						Summary of Findings					Confidence (in effect)
						ES	Usual care	Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)		
						(5.7)	(6.2)				
Fugl-Meyer Assessment - Upper Limb (total) (1 month follow-up: Low dose FES) (Better indicated by higher values)											
1 Hsu, 2010 [117]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision(d)	Hsu: 28.1 (18)	Hsu: 14.2 (14.5)	13.90 (4.24, 23.56)	MD 13.90 higher (4.24 to 23.56 higher)		Low
Fugl-Meyer Assessment - Upper Limb (total) (3 months follow-up) (Better indicated by higher values)											
3 Chae 1998[41]; Hsu, 2010 [117]; Lin, 2011[155]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	Chae: 20.6 (15.1) Hsu (high dose): 32.8 (23.7) Lin: 26.0 (5.1)	Chae: 11.2 (8.7) Hsu: 17 (15.4) Lin: 18.5 (6.7)	8.45 (5.05, 11.85)	MD 8.45 higher (5.05 to 11.85 higher)		Moderate
Fugl-Meyer Assessment - Upper Limb (total) (3 months follow-up: Low dose FES) (Better indicated by higher values)											
1 Hsu, 2010 [117]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision(d)	Hsu: 36.7 (19.5)	Hsu: 17 (15.4)	19.70 (9.32, 30.08)	MD 19.7 higher (9.32 to 30.08 higher)		Low
Fugl-Meyer Assessment - Upper Limb (total) (6 months follow-up) (Better indicated by higher values)											

Quality assessment						Summary of Findings					Confidence (in effect)
						ES	Usual care	Effect			
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)		
Lin, 2011 [155]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision(d)	29.8 (3.6)	20.3 (12.3)	9.5 (3.59 to 15.41)	MD 9.5 higher (3.59 to 15.41 higher)	Low	
Modified Ashworth Scale (3 Weeks follow-up) (Better indicated by higher values)											
Lin, 2011 [155]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision(f)	1.16 (0.50)	0.78 (0.55)	0.38 (0.04 to 0.72)	MD 0.38 higher (0.04 to 0.72 higher)	Low	
Modified Ashworth Scale (1 month follow-up) (Better indicated by higher values)											
Lin, 2011 [155]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision(f)	1.42 (0.51)	1.11 (0.32)	0.31 (0.04 to 0.58)	MD 0.31 higher (0.04 to 0.58 higher)	Low	
Modified Ashworth Scale (3 months follow-up) (Better indicated by higher values)											
Lin, 2011 [155]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Very serious imprecision(n)	1.56 (0.53)	1.50 (0.53)	0.06 (-0.28 to 0.40)	MD 0.06 higher (-0.28 lower to 0.40 higher)	Very low	

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
Modified Ashworth Scale (6 months follow-up) (Better indicated by higher values)										
Lin, 2011 [155]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision(f)	1.67 (0.52)	1.86 (0.38)	-0.19 (-0.48 to 0.1)	MD 0.19 lower (0.48 lower to 0.1 higher)	Low
Modified Barthel Index (3 weeks follow-up) (Better indicated by higher values)										
Lin, 2011 [155]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision(l)	57.0 (10.7)	49.7 (11.4)	7.3 (0.17 to 14.43)	MD 7.3 higher (0.17 to 14.43 higher)	Low
Modified Barthel Index (1 month follow-up) (Better indicated by higher values)										
Lin, 2011 [155]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	Serious imprecision(l)	64.5 (10.4)	55.7 (12.1)	8.80 (1.51 to 16.09)	MD 8.8 higher (1.51 to 16.09 higher)	Low
Modified Barthel Index (3 months follow-up) (Better indicated by higher values)										
Lin,	RCT- Single	Serious	No serious	No serious	No serious	72.4 (8.5)	59.3	13.10(6.37	MD 13.1	Moderate

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
2011 [155]	blinded	limitations(b)	inconsistency	indirectness	imprecision		(12.0)	to 19.83)	higher (6.37 to 19.83 higher)	
Modified Barthel Index (6 months follow-up) (Better indicated by higher values)										
Lin, 2011[155]	RCT- Single blinded	Serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	79.2 (5.2)	66.1 (11.3)	13.1 (7.38 to 18.82)	MD 13.1 higher (7.38 to 18.82 higher)	Moderate
Electrophysiological evaluation - Fmax/Mmax (%) Post intervention (Better indicated by higher)										
Sahin 2012 [227]	RCT- Double blinded	No serious limitation	No serious inconsistency	No serious indirectness	Very serious imprecision (o)	3.6 (3.0)	3.5 (2.9)	0.10 (-1.68, 1.88)	MD 0.10 higher (1.68 lower to 1.88 higher)	Low
Electrophysiological evaluation - Hmax/Mmax (%) Post intervention (Better indicated by higher)										
Sahin 2012 [227]	RCT- Double blinded	No serious limitation	No serious inconsistency	No serious indirectness	No serious imprecision	0.27 (0.15)	0.25 (0.19)	0.02 (-0.08, 0.12)	MD 0.10 higher (1.68 lower to 1.88 higher)	High

Quality assessment						Summary of Findings				
						ES	Usual care	Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Number of event / Total N Mean (SD)/ Median (IQR)	Number of event / Total N Mean (SD)/Median (IQR)	Relative Risk Mean difference (95% CI)/ P values	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
Wrist spasticity – Modified Ashworth Scale Post intervention (Better indicated by higher)										
Sahin 2012 [227]	RCT- Double blinded	No serious limitation	No serious inconsistency	No serious indirectness	(i)	1.8	2	(i)	(i)	High
Brunnstrom motor scale (upper) Post intervention (Better indicated by higher)										
Sahin 2012 [227]	RCT- Double blinded	No serious limitation	No serious inconsistency	No serious indirectness	(i)	4.5	4	(i)	(i)	High

(a) Both studies were unblinded with unclear randomization and allocation concealment.
(b) Unclear randomization and allocation concealment.
(c) Confidence interval crossed one end of default MID.
(d) Mean difference did not reach the agreed MID (10% difference in the scale).
(e) Confidence interval crossed both ends of default MID.
(f) Mean difference did not reach the default MID.
(g) Unclear blinding, randomization and allocation concealment.
(h) Mean difference did not reach the agreed MID of 12 points.
(i) Imprecision could not be assessed as authors reported only median (IQR). Results could not be meta-analysed and relative/absolute effect could not be estimated.
(j) P value as reported by authors.
(k) Inadequate allocation concealment.
(l) Mean difference did not reach the agreed MID (9.25).
(m) Confidence interval crossed both ends of the default MID.
(n) Items of the original scale not included.
(o) Confidence interval crosses both ends of default MID

Narrative summaries

The following studies are summarised as a narrative because the results were not presented in numerical data that could be included in the GRADE table:

Cauraugh et al, 2000[38] found that the experimental group who received the FES training moved significantly more blocks and displayed a higher isometric force impulse after the rehabilitation treatment compared to usual care group. Neither Motor Assessment Scale nor Fugl-Meyer tests were significantly different between the two groups.

Cauraugh et al, 2002[39] found significant findings favouring the coupled bilateral movement training and EMG-triggered neuromuscular stimulation group. In addition, the unilateral movement/stimulation group exceeded the control across the categories of tasks.

Thrasher et al, 2008[257] found that the FES group improved significantly more than the control group in terms of object manipulation, palmer grip torque, and pinch grip pulling force, Barthel Index, Upper Extremity Fugl-Meyer scores and Upper Extremity Chedoke-McMaster stages of Motor Recovery.

Hara et al, 2008[104] reported that the FES group displayed significantly greater improvements in the active Range of Movement of wrist and finger extension and shoulder flexion, modified Ashworth scale (MAS) and functional hand tests and was able to smoothly perform activities of daily life using the hemiplegic upper extremities.

13.4.1.2 Economic evidence

Literature review

No relevant economic evaluations comparing ES with usual care were identified.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

Typical costs for FES were obtained from Odstock Medical Limited at Salisbury District Hospital (by email, 20-21st December 2010) who supply the FES system described in the RCT reported by Mann et al (2005)[168] included in the clinical review (the Microstim 2 [MS2v2], a self-contained two channel exercise stimulator). The cost of the MS2v2 kit is £267 (excluding VAT). The device is guaranteed for 2 years and spare parts and service maintenance are offered for a minimum of 5 years. The electrodes are single patient use and last around four weeks. Electrodes cost between £6 and £10 per pack of four (excluding VAT) depending on size and quality. The device will run on standard or rechargeable PP3 batteries (supplied in kit). The cost of a standard 6-month treatment package using the MS2v2 system consisting of one initial assessment and five treatment sessions is charged at £840; each session is £140. This includes the cost of all equipment, consumables, physiotherapy and hospital overheads and is delivered as an outpatient service. Patients can also use the MS2v2 daily in their own homes. Based on the standard treatment package cost, for FES to be judged cost effective it would need to provide benefits to patients that translated to at least an additional 0.042 QALYs per person.

13.4.1.3 Evidence statements

Clinical evidence statements

Two studies[6,7] comprising of 41 participants found that participants who received the Electrical Stimulation experienced a statistically significant improvement in the Box and Blocs test at the end of the trial compared to participants who received usual care (LOW CONFIDENCE IN EFFECT).

One study[137] comprising of 16 participants found no significant difference in the Box and Blocks test at the end of the trial between participants who received the Electrical Stimulation and those who received sham treatment (LOW CONFIDENCE IN EFFECT).

Two studies[6,7] comprising of 41 participants found that participants who received the Electrical Stimulation experienced a statistically significant improvement in the Jebsen-Taylor Hand Function test (light cans) at the end of the trial compared to participants who received usual care (LOW CONFIDENCE IN EFFECT).

One study[137] comprising of 16 participants found a statistically significant improvement in the Jebsen-Taylor Hand Function test (light cans) at the end of the trial for participants who received the Electrical Stimulation compared to those who received sham treatment (MODERATE CONFIDENCE IN EFFECT).

Two studies[6,7] comprising of 41 participants found that participants who received the Electrical Stimulation experienced a statistically significant improvement in the Modified Fugl-Meyer

Assessment at the end of the trial compared to participants who received usual care (VERY LOW CONFIDENCE IN EFFECT).

One study[42] comprising of 20 participants found that participants received the Electrical Stimulation had significantly higher scores in the Functional Test for the Hemiplegic Upper Extremity at the end of the trial compared to the usual care group (MODERATE CONFIDENCE IN EFFECT).

One study[42] comprising of 20 participants found no significant difference on the following outcomes between the Electrical Stimulation and the usual care groups at the end of the trial:

- forward reach distance (cm) (LOW CONFIDENCE IN EFFECT),
- active range of motion in wrist extension (VERY LOW CONFIDENCE IN EFFECT),
- grip power (kg) (LOW CONFIDENCE IN EFFECT),
- Functional Independence Measure (LOW CONFIDENCE IN EFFECT),
- Modified Ashworth Scale of shoulder (LOW CONFIDENCE IN EFFECT),
- Modified Ashworth Scale of elbow (LOW CONFIDENCE IN EFFECT),
- Modified Ashworth Scale of wrist (LOW CONFIDENCE IN EFFECT)

Two studies [42], [227] comprising 62 participants found no significant difference with the range of motion in wrist extension between the Electrical Stimulation and the usual care groups at the end of the intervention (HIGH CONFIDENCE IN EFFECT)

Three studies[41];[42]; [227] comprising of 90 participants found no significant difference in the Functional Independence Measure between the Electrical Stimulation group and the usual care group post treatment (MODERATE CONFIDENCE IN EFFECT)

One study[41] comprising of 28 participants found no significant difference in the Functional Independence Measure between the Electrical Stimulation group and the usual care group at 4 and 12 weeks follow-up (MODERATE CONFIDENCE IN EFFECT)

One study[137] comprising of 16 participants found no significant difference on the following outcomes between the Electrical Stimulation and the usual care groups at the end of the trial:

- Strength of finger extension (LOW CONFIDENCE IN EFFECT),
- Motor Activity Log; amount of use score (LOW CONFIDENCE IN EFFECT),
- Motor Activity Log; how well used score (LOW CONFIDENCE IN EFFECT),
- Jebsen-Taylor Hand Function test (page turn) (LOW CONFIDENCE IN EFFECT),
- Jebsen-Taylor Hand Function test (heavy scans) (VERY LOW CONFIDENCE IN EFFECT).

One study[117] comprising of 66 participants found statically significant improvement in the following outcomes between the Electrical Stimulation and the usual care groups

- Motor Activity Log: amount of use score – low dose (LOW CONFIDENCE IN EFFECT),
- Motor Activity Log: amount of use score – high dose (LOW CONFIDENCE IN EFFECT),
- Motor Activity Log: quality of movement – low dose (LOW CONFIDENCE IN EFFECT),
- Motor Activity Log: quality of movement – high dose (LOW CONFIDENCE IN EFFECT)

One study[137] comprising of 16 participants found a statistically significant improvement in the following outcomes at the end of the trial for participants who received the Electrical Stimulation compared to those who received sham treatment:

- Jebsen-Taylor Hand Function test (small objects) (MODERATE CONFIDENCE IN EFFECT),
- Jebsen-Taylor Hand Function test (feeding) (MODERATE CONFIDENCE IN EFFECT),
- Jebsen-Taylor Hand Function test (stacking) (MODERATE CONFIDENCE IN EFFECT),

- Finger tracking accuracy test (LOW CONFIDENCE IN EFFECT).

One study[210] comprising of 16 participants found a statistically significant improvement in the following outcomes for the higher functioning participants who received the Electrical Stimulation compared to those who received usual care:

- Upper Extremity Function Test (at the end of the trial and at 26 weeks follow-up) (MODERATE CONFIDENCE IN EFFECT),
- Drawing test (at the end of the trial and at 26 weeks follow-up) (LOW CONFIDENCE IN EFFECT),
- Ashworth grade (at 26 weeks follow-up) (MODERATE CONFIDENCE IN EFFECT),
- Reduced Upper Extremity Motor Activity Log Questionnaire- amount scale (at 26 weeks follow-up) (LOW CONFIDENCE IN EFFECT),
- Reduced Upper Extremity Motor Activity Log Questionnaire- how well scale (at 26 weeks follow-up) (LOW CONFIDENCE IN EFFECT).

One study[210] comprising of 12 participants found a statistically significant improvement in the following outcomes for the lower functioning participants who received the Electrical Stimulation compared to those who received usual care:

- Upper Extremity Function Test (at the end of the trial and at 26 weeks follow-up) (MODERATE CONFIDENCE IN EFFECT),
- Drawing test (at 26 weeks follow-up) (LOW CONFIDENCE IN EFFECT),
- Reduced Upper Extremity Motor Activity Log Questionnaire- amount scale (at 26 weeks follow-up) (LOW CONFIDENCE IN EFFECT),
- Reduced Upper Extremity Motor Activity Log Questionnaire- how well scale (at 26 weeks follow-up) (LOW CONFIDENCE IN EFFECT).

One study[117] comprising 66 participants found no difference in the change scores of Action Research Arm Test (total score) between the group that received low dose ES and the usual care group at 4 weeks follow-up (LOW CONFIDENCE IN EFFECT).

One study[117] comprising 66 participants found no difference in the change scores of Action Research Arm Test (total score) between the group that received high dose ES and the usual care group at 4 weeks follow-up (LOW CONFIDENCE IN EFFECT).

One study[117] comprising 66 participants found a statistically significant improvement in the change scores of Action Research Arm Test (total score) between the group that received low dose ES and the usual care group at 12 weeks follow-up (LOW CONFIDENCE IN EFFECT).

Two studies[168]; [117] comprising of 88 participants found a statistically significant improvement in the change scores of Action Research Arm Test (total score) at 12 weeks follow-up for the participants who received the Electrical Stimulation compared to those who received usual care (LOW CONFIDENCE IN EFFECT).

One study[168] comprising of 22 participants found a statistically significant improvement in the change scores of Action Research Arm Test (total score) at 24 weeks follow-up for the participants who received the Electrical Stimulation compared to those who received usual care (VERY LOW CONFIDENCE IN EFFECT).

Three studies [41,42,155] comprising of 85 participants found that participants who received the Electrical Stimulation experienced a statistically significant improvement (post treatment) in the Fugl-Meyer Assessment compared to participants who received usual care. This difference was of clinical importance (MODERATE CONFIDENCE IN EFFECT).

Three studies [41,117,155] comprising of 109 participants found that participants who received the Electrical Stimulation experienced a statistically significant improvement in the Fugl-Meyer Assessment compared to participants who received usual care at one month follow-up. This difference was of clinical importance (MODERATE CONFIDENCE IN EFFECT).

One study[117] comprising of 66 participants found that participants who received low dose Electrical Stimulation experienced a statistically significant improvement in the Fugl-Meyer Assessment compared to participants who received usual care at one month follow-up. This difference was not of clinical importance (LOW CONFIDENCE IN EFFECT).

Three studies [41,117,155] comprising of 109 participants found that participants who received the Electrical Stimulation experienced a statistically significant improvement in the Fugl-Meyer Assessment compared to participants who received usual care at 3 months follow-up. This difference was of clinical importance (MODERATE CONFIDENCE IN EFFECT).

One study[117] comprising of 66 participants found that participants who received low dose Electrical Stimulation experienced a statistically significant improvement in the Fugl-Meyer Assessment compared to participants who received usual care at 3 months follow-up. This difference was not of clinical importance (LOW CONFIDENCE IN EFFECT).

One study[155]comprising of 46 participants found that participants who received the Electrical Stimulation experienced a statistically significant improvement in the Fugl-Meyer Assessment at 6 months follow-up compared to participants who received usual care. This difference was not of clinical importance (LOW CONFIDENCE IN EFFECT).

One study[155]comprising of 46 participants found that participants who received the Electrical Stimulation experienced a statistically significant improvement post treatment and 1 month follow-up with the modified Ashworth scale compared to participants who received usual care (LOW CONFIDENCE IN EFFECT).

One study[155]comprising of 46 participants found no significant improvement with the modified Ashworth scale at 3 months follow-up between the Electrical Stimulation and the usual care groups (VERY LOW CONFIDENCE IN EFFECT).

One study[155]comprising of 46 participants found no significant improvement with the modified Ashworth scale at 6 months follow-up between the Electrical Stimulation and the usual care groups (LOW CONFIDENCE IN EFFECT).

One study[155]comprising of 46 participants found that participants who received the Electrical Stimulation experienced a statistically significant improvement in the modified Barthel Index at post treatment and 1 month follow-up compared to participants who received usual care. This difference was not of clinical importance (LOW CONFIDENCE IN EFFECT).

One study[155]comprising of 46 participants found that participants who received the Electrical Stimulation experienced a statistically significant improvement in the modified Barthel Index at 3 and 6 months follow-up compared to participants who received usual care (MODERATE CONFIDENCE IN EFFECT).

One study[227] comprising 42 participants found no significant difference in electrophysiological evaluation (Fmax/Mmax) between the Electrical Stimulation and the usual care group (LOW CONFIDENCE IN EFFECT)

One study [227] comprising 42 participants found no significant difference in electrophysiological evaluation (Hmax/Mmax) between the Electrical Stimulation and the usual care group (HIGH CONFIDENCE IN EFFECT)

Economic evidence statements

No cost effectiveness evidence was identified.

13.4.2 Recommendations and link to evidence

	90. Do not routinely offer people with stroke electrical stimulation for their hand and arm. **91. Consider a trial of electrical stimulation in people who have evidence of muscle contraction after stroke but cannot move their arm against resistance.** **92. If a trial of treatment is considered appropriate, ensure that electrical stimulation therapy is guided by a qualified rehabilitation professional.** **93. The aim of electrical stimulation should be to improve strength while practising functional tasks in the context of a comprehensive stroke rehabilitation programme.** **94. Continue electrical stimulation if progress towards clear functional goals has been demonstrated (for example, maintaining range of movement, or improving grasp and release).**
Relative values of different outcomes	A wide range of measures were used in these studies and the GDG noted that there was no psychometrically robust patient-reported outcome measure used for assessment of reduced upper limb function. The wide range of measures reported within the trials reviewed makes interpreting the data difficult.
Trade-off between clinical benefits and harms	There are few risks associated with Electrical Stimulation. The commonest is a skin reaction when self-adhesive electrodes are used. Benefits arise from the increased range of movements produced by ES with the associated increased ease of performance of functional task. ES was typically targeted at finger and wrist extensors but was also used for elbow extension and shoulder flexion. The GDG were also aware of the use of electrical stimulation for management of spasticity however this was not included in review.
Economic considerations	No cost-effectiveness studies were found for this question. ES for hand functions are not routinely used in the UK NHS currently. A typical cost per patient of delivering ES was estimated to be around £840 (one initial assessment followed by five sessions in-hospital). Based on these costs, for ES to be judged cost effective it would need to provide benefits to patients that translated to at least an additional 0.042 QALYs per person. The GDG considered this additional benefit achievable in a selected population for whom the treatment is considered appropriate (for example people who have evidence of

	muscle contraction after stroke but cannot move their arm against resistance).
Quality of evidence	The majority of the studies reported benefit but this was not always significant. The GDG considered that the results should be interpreted with caution due to the small sample size of the studies. Very few studies reported follow-up results but Popovic[210], Mann[168], Powell[213], Lin [155] did report statistical significance in favour of ES between 1 and six months follow-up for a range of outcomes including Fugl-Meyer Assessment and modified Barthel Index. The studies could be divided into those that looked at early after stroke, late after stroke and those that incorporated physiotherapy guided functional exercise and those that did not. The GDG observed that the Kimberley study [137] was the only one that did not have physiotherapy as the comparator and it was noted that generally the patients included in the studies tended to be the younger age group (between 45-70 years old). The GDG considered that when used early after stroke in high functioning people there appeared to be limited evidence of benefit [6,210] but a larger study is needed. The GDG also noted that the studies by Alon[6,7] used a modified Fugl-Meyer Assessment outcome and therefore the results shown would need to be regarded with caution.
Other considerations	The GDG noted that the study by Alon[6,7] was partially sponsored by the manufacturers of the device and that the results were consistent with other studies which were publicly or charity funded. Electrical stimulation is not widely available, and if a trial of treatment is offered to a patient it should only be delivered by a health professional with the appropriate skill set. The GDG agreed that an assessment of those who may benefit from the intervention should be carried out and a trial of use conducted to establish if an improvement in range of movement or function of the hand or wrist is clearly demonstrated.

13.5 Constraint induced movement therapy

Constraint induced movement therapy is an approach to promote increased activity in the impaired upper limb in patients after stroke. In order to overcome 'learned non-use' in the affected limb the unaffected limb is restrained usually by a hand mitten or arm sling for long periods of the day, thereby promoting the use of the affected limb in everyday situations. In addition to the restraint, treatment includes periods of intensive focused exercise or activity usually under the guidance of a therapist. Because of the nature of the intervention constraint induced movement therapy is not suitable for, or acceptable to, all patients after stroke.

13.5.1 Evidence review: In people after stroke what is the clinical and cost effectiveness of constraint induced therapy versus usual care on improving function and reducing disability?

Clinical Methodological Introduction	
Population	Adults and young people 16 or older who have had a stroke
Intervention	Constraint induced movement therapy (CIMT) for upper limb Subgroup analysis Less than 5 hours More than 5 hours Any constraint – e g slings
Comparison	Usual care

Clinical Methodological Introduction	
Outcomes	• Functional Independence Measure (FIM) • Barthel Index • Fugl-Meyer Assessment • Action Research Arm Test (ARAT) • Wolf Motor Function Test (WMFT) • 9 hole peg test • Any adverse event

13.5.1.1 Clinical evidence review

Searches were conducted for systematic reviews and RCTs comparing Constraint Induced Movement Therapies (CIMTs) with usual care for improving upper limb function and reducing disability in people after stroke. Only studies with a minimum sample size of 20 participants (10 in each arm) and including at least 50% of participants with stroke were selected. Fifteen (15) RCTs were identified. Table 1 summarises the population, intervention, comparison and outcomes for each of the studies.

Table 103: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix H.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Dahl, 2008[54]	Inpatients after stroke (2 weeks-8 years post-stroke) with unilateral hand impairment but more than 20 degrees active wrist extension and 10 degrees active finger extension.	CIMT: a mitten immobilised the non-paretic hand for target 90% of waking hours (actually 13 hours/day). Training provided in groups of 4 participants led by physical and occupational therapists and assisted by trained nurses for 6 hours/day for 10 consecutive week days; exercises and activities chosen from 150 in 10 fields (including personal care, kitchen/household etc.). (N=18)	Usual care: community-based follow-up according to patient's needs, involving both upper and lower limb training and could include inpatient rehabilitation (physiotherapy plus occupational therapy) following 2 outpatient sessions per week. (N=12)	• Wolf Motor Function Test (WMFT) • Functional Independence Measure (FIM)
Dromerick, 2000[72]	Inpatients in acute stroke & brain injury rehabilitation service (admission within 14 days of ischemic stroke) with persistent hemiparesis leading to	CIMT: a padded mitten immobilised the non-paretic hand for at least 6 hours/day during the 14-day treatment period. Treatment was directed towards subject attention and effort toward the hemiparetic upper extremity and	Usual care: traditional occupational therapy plus a circuit training program allowing patients to perform bilateral self-range of motion and functional activities in a supervised setting for 2 hours/day, 5	• Action Research Arm Test (ARAT) • Barthel Index • Functional Independence Measure (FIM)

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
	impaired upper extremity function. Details on patient's wrist and finger extension ability were not reported.	minimised the use of the uninvolved upper extremity during functional activities. All subjects also received routine interdisciplinary stroke rehabilitation; individualised circuit-training techniques 2 hours/day, 5 days/week for 2 consecutive weeks. (N=11)	days/week for 2 consecutive weeks. (N=9)	
Hammer, 2009[102]	Patients after stroke (1-6 months post stroke) with ability to move the shoulder and elbow voluntarily and extend 20 degrees in the wrist and 10 degrees in the fingers of the paretic arm and hand.	Forced-used sling: a restraining sling immobilised the unaffected arm with a target of 6 hours/day (actually achieved 3.7 hours/day) for 5 days/week for 2 weeks. Patients also received individualised physical and occupational therapy for the upper and lower limb training based on and task-orientated approach. (N=15)	Usual care: standard interdisciplinary rehabilitation of daily training 5 days/week (without forced-use).(N=15)	• Fugl-Meyer Assessment • Action Research Arm Test (ARAT)
Lin, 2009[153]	Chronic unilateral stroke patients (>6 months post onset of ischemic or hemorrhagic stroke) with Brunnstrom above stage III for proximal and distal part of upper limb; an amount of use score <2.5 on the motor Activity log of the upper limb and Modified Ashworth scale score ≤2 in any joint of the shoulder, elbow wrist, or fingers.	Distributed CIMT: a mitten restricted the movement of unaffected hand for 6 hours/day. Patients also received intensive training of affected upper limb in functional tasks for 2 hours/weekday for 3 weeks. (N=20)	Usual care: training in hand function, coordination, balance, movements of affected upper limb and practice on functional tasks with unaffected or both limbs. (N=20)	• Fugl-Meyer Assessment (FMA) • Functional Independence Measure (FIM)

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Lin, 2007[154]	Chronic stroke patients (13-26 months post first cerebrovascular incident) with Brunnstrom above stage III for proximal and distal part of arm; an amount of use score <2.5 on the motor Activity log of the affected arm and Modified Ashworth scale score = 2 in any joint of the shoulder, elbow wrist, or fingers.	Modified CIMT: a mitt restricted the movement of unaffected hand for a target of 6 hours/day (actual 6.2 hours/day) for 3 weeks plus intensive training of affected arm supervised by trained occupational therapists for 2 hours/ weekday. (N=17)	Usual care: involving strength, balance and fine motor dexterity training, functional task practice when possible, and stretching/weight bearing by the affected arm. (N=17)	• Functional Independence Measure (FIM)
Myint, 2008[182]	Stroke patients (2-16 weeks after stroke) with hemiparesis of the affected limb and with minimal movement of ≥ 20 degrees wrist extension and 10 degrees extension of all digits	CIMT: patients wearing a padded shoulder sling for 90% of waking hours). Patients also received 4 hours /day for 5 days/week for 2 weeks supervised activities including shaping (a behavioural method to improve motor performance in small steps and encouraging positive feedback). (N=28)	Usual care: conventional occupational and physical therapy involving neurodevelopmental techniques, bimanual tasks, compensatory techniques, strength, range of motion, positioning, mobility for 4 hours /day for 5 days/week for 2 weeks. (N=20)	• Action Research Arm Test (ARAT) • Barthel Index • 9hole peg test
Page, 2008[197]	Chronic stroke patients (>12 months post-stroke) able to selectively actively extend at least 10 degrees at the metacarpophalangeal and interphalangeal joints and 20 degrees at the wrist.	Modified CIMT: sling and hand in mesh polystyrene-filled mitt restricted the use of unaffected arm for 5 hours/weekday during a time of frequent arm use. Patients also received training of the more affected arm therapy using shaping techniques for half-hour one-to-one sessions for 3 days per week for 10 weeks assisted by therapists. (N=13)	Usual care: time matched rehabilitation focusing on proprioceptive neuromuscular facilitation techniques, stretching and compensatory techniques. (N=12)	• Action Research Arm Test (ARAT) • Fugl-Meyer assessment (FMA)
Ploughman,	In- or out-	Forced-use CIMT:	Usual care:	• Action Research

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
2004[206]	patients with first stroke (less than 16 weeks post stroke) showing minimal movement of the arm and hand (in tertiary mixed rehabilitation centre). Motor control of the upper extremity of more than stage 2 but not more than stage 6 on the Chedoke-McMaster Impairment Inventory (CMII) of the arm and hand.	patients wearing thick constraint knitted acrylic thumbless mitten to discourage use of unaffected arm and hand; worn for 1 hour per day increasing to 6 hours by 2 weeks and 6 hours towards the end of treatment. (N=13)	conventional therapy by facilitating the proximal motor control progressing to skilled task training, strength and endurance training, functional electrical stimulation, gait training, education. (N=14)	Arm Test (ARAT) • Functional Independent Measure (FIM)
Taub, 2006[254]	Chronic stroke patients (mean=4.5 years after stroke) with motor deficit; ability to actively extend≥ 10 degrees at metacarpophalangeal and interphalangeal joints and 20 degrees at wrist.	CIMT: a resting hand splint/sling on the unaffected upper extremity prevented use of that arm for a target of 90% of waking hours for 6 hours/day for 10 consecutive weekdays. Training on the paretic arm consisted of 'shaping' (a behavioural method to improve motor performance in small steps and encouraging positive feedback). (N=21)	Usual care: program of physical fitness, cognitive, and relaxation exercises for the same length of time and with the same amount of interaction with the therapists as the intervention group. (N=20)	• Wolf Motor Function Test (WMFT)
van der Lee, 1999[270]	Patients after single stroke (at least 1 year post stroke) with hemiparesis on the dominant side and with a minimum of 20 degrees of active wrist extension and 10 degrees of finger extension	Forced use treatment: unaffected arm was immobilised using splint (worn at home) for 6 hours/ day for 5 days/week during 12 days of treatment plus a closed arm sling was attached to the waist during the treatment hours. (N=33)	Usual care: involving neurodevelopmental bimanual training provided in groups of 4 participants (housekeeping activities, handicrafts, games) (N=33)	• Fugl-Meyer Assessment (FMA) • Action Research Arm Test (ARAT)
Wolf,	Patients with	CIMT: mitt restricted	Usual care: ranged	• Wolf Motor

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
2006[286]	first-time clinical ischemic or hemorrhagic cerebrovascular accident (3-6 months after stroke). Lower functioning participants had at least 10 degrees of active wrist extension, at least 10 degrees of thumb abduction/extension, and at least 10 degrees of extension in at least 2 additional digits. These movements had to be repeated 3 times in 1 minute.	the use of unaffected hand for a goal of 90% of waking hours for a total of 14 days (treatment days plus weekends); the patients also received adaptive task practice and standard task training of paretic limb for 6 hours /day on weekdays (N=106)	from no treatment to application of mechanical interventions (orthotics) or various occupational and physical therapy approaches at home as a day patient or as an outpatient. (N=116)	Function Test (WMFT)
Wu, 2007 (a) [291]	First time stroke patients(3 weeks to 37 months post onset with Brunnstrom above stage III for proximal part of upper limb; an amount of use score <2.5 on the Motor Activity log of the upper limb; no serious cognitive deficits.	CIMT: mitt restricted the use of less affected hand for 6 hours/day for 5 days/week for 3 weeks and patients also received typical training activities for daily tasks involving the use of more affected limb (2 hours/day). Also received interdisciplinary rehabilitation (1.5 hours/day for 5 days/week). (N=24)	Usual care: neurodevelopmental therapy emphasising functional task practice, stretching and weight bearing with more affected arm and fine-motor dexterity for 2 hours/day. Also received interdisciplinary rehabilitation (1.5 hours/day for 5 days/week). (N=23)	• Fugl-Meyer Assessment (FMA)
Wu, 2007 (b) [292]	Elderly stroke patients (mean age 72 years) with 0.5-31 months post onset of a first-ever stroke with considerable non-use of the affected limb (an amount of use score <2.5 on the Motor	Modified CIMT: a mitt was applied in the unaffected hand for 6 hours /weekday at time of frequent arm use for 3 weeks. Patients also received individualised 2-hour therapy sessions for 5 times/week involving shaping and adaptive repetitive tasks focusing on daily	Usual care: 2 hour therapy session with 75% of time spent on neurodevelopmental techniques emphasising functional task practice, stretching, weight bearing, fine motor dexterity and 25% on compensatory	• Fugl-Meyer Assessment (FMA) • Functional Independence Measure (FIM)

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
	Activity log); Modified Ashworth scale score ≤2 in any joint	activities and 15 minutes of therapy on normalising muscle tone. (N=13)	techniques. (N=13)	
Wu, 2007 (c) [293]	Post stroke patients (12-36 months post stroke of a first-ever cerebrovascular accident) with an ability to actively extend at least 10 degrees at the metacarpophalangeal and interphalangeal joints and 20 degrees at the wrist.	Modified CIMT: a mitt was applied in the unaffected hand for 6 hours /weekday at time of frequent arm use for 3 weeks. Training administered intensively 2 hours per day, 5 days per week, for 3 weeks. Training took place during scheduled occupational therapy sessions, and other routine interdisciplinary stroke rehabilitation proceeded as usual. (N=15)	Usual care: patients received training matched to the mCIMT in duration and intensity of occupational therapy activities. (N=15)	• Functional Independence Measure (FIM)
Wu, 2011[294]	Patients after stroke (mean post stroke 16.2 months) and mild to moderate motor impairment with Brunnstrom above stage III for proximal part of upper extremity; an amount of use score <2.5 on the Motor Activity log.	1) Distributed CIMT: a mitt restricted the unaffected hand for 6 hours/day and intensively trained the affected upper extremity in functional tasks. (N=22) 2) Bilateral arm training focusing on the simultaneous movements in symmetric or alternating patterns of both upper extremities in functional tasks. (N=22) Study duration: 2 hours/day, 5 days/week for 3 weeks	Usual care: patients received compensatory practice on functional tasks with the unaffected upper extremity or both upper extremities. (N=22)	• Wolf Motor Function Test (WMFT)

Comparison: constraint Induced movement therapies versus usual care

Table 104: Constraint induced movement therapy (CIMT) versus usual care - clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	CIMT Mean (SD)/ Frequencies (%)	Usual care Mean (SD)/ Frequencies (%)	Mean difference/ Risk Ratio (95% CI)	Absolute Effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
Action Research Arm Test (post treatment) (Better indicated by higher values)										
4 Dromerick 2000[72] ; Myint 2008[182] ; Page 2008[197]; Van der Lee 1999[270]	RCTs- single blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision (b)	Dromerick 2000: 52.8 (5.9) Myint 2008: 47.1 (10.2) Page 2008: 40.54 (8.18) Van der Lee: 39.2 (13.1)	Dromerick 2000: 44.3 (11.1) Myint 2008: 33.6 (12.5) Page 2008: 29.17 (10) Van der Lee: 30 (13.9)	10.78 (7.27, 14.30)	MD 10.78 higher (7.27 to 14.30 higher)	Low
Action Research Arm Test (4 weeks follow-up) (Better indicated by higher values)										
1 Van der Lee 1999[270]	RCT- single blinded	No serious limitation	No serious inconsistency	No serious indirectness	Serious imprecision (b)	38 (12.3)	30.8 (13.6)	MD 7.20 (0.94, 13.46)	MD 7.20 higher (0.94 to 13.46 higher)	Moderate
Action Research Arm Test (12 weeks follow-up) (Better indicated by higher values)										

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	CIMT Mean (SD)/ Frequencies (%)	Usual care Mean (SD)/ Frequencies (%)	Mean difference/ Risk Ratio (95% CI)	Absolute Effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
1 Myint 2008[182]	RCT- single blinded	Serious limitations(a)	No serious indirectness	No serious indirectness	No serious imprecision	49. 6 (9.9)	39.9(14.1)	MD 9.7 (2.51, 16.89)	MD 9.7 higher (2.51 to 16.89 higher)	Moderate
Action Research Arm Test (10 months follow-up) (Better indicated by higher values)										
1 Van der Lee 1999[270]	RCT- single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (b)	38.5 (13.6)	30.7 (14.2)	MD 7.80 (1.09, 14.51)	MD 7.80 higher (1.09 to 14.51 higher)	Moderate
Wolf Motor Function Test (performance time) (post treatment) (Better indicated by lower values)										
3 Dahl 2008[54] ; Taub 2006[254]; Wu 2011[294]	RCTs- single blinded	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision(e)	Dahl 2008: 1.56 (0.57) Taub 2010:3 (1.1) Wu 2011:4.02 (2.49)	Dahl 2008: 2.03 (0.82) Taub 2010:4.6 (4.4) Wu 2011:5.83 (4.65)	MD -0.53 (-0.91, -0.16)	MD 0.53 lower (0.91 to 0.16 lower)	Low
Wolf Motor Function Test (performance time) (6 months follow-up) (Better indicated by lower values)										
1 Dahl 2008[54]	RCT- single blinded	Serious limitations(d)	No serious inconsistency	No serious indirectness	Serious imprecision(e)	1.82 (0.8)	1.77 (0.92)	MD 0.05 (-0.59, 0.69)	MD 0.05 higher (0.59 lower to 0.69	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	CIMT Mean (SD)/ Frequencies (%)	Usual care Mean (SD)/ Frequencies (%)	Mean difference/ Risk Ratio (95% CI)	Absolute Effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
									higher)	
Change in Wolf Motor Function Test (performance time) (12 months follow-up)										
1 Wolf 2006[286]	RCT-single blinded	No serious limitations	No serious inconsistency	No serious indirectness	No serious imprecision	(f)	(f)	MD 34.00 (14.50, 53.50)	MD 34.00 higher (14.50 to 53.50 higher)	High
Wolf Motor Function Test (functional ability) (post-treatment) (Better indicated by higher values)										
3 Dahl 2008[54]; Taub 2006[254]; Wu 2011[294]	RCTs- single blinded	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision(e)	Dahl 2008:3.85 (0.5) Taub 2010: 3.2 (0.4) Wu 2011:3.78 (0.71)	Dahl 2008:3.47(0.6) Taub 2010:2.9(0.5) Wu 2011:3.66 (0.87)	MD 0.46 (0.08, 0.83)	MD 0.46higher (0.08 to 0.83higher)	Low
Wolf Motor Function Test (functional ability) (6 months follow-up) (Better indicated by higher values)										
1 Dahl 2008[54]	RCT- single blinded	Serious limitations(d)	No serious inconsistency	No serious indirectness	Serious imprecision(e)	3.95 (0.61)	3.73 (0.58)	MD 0.22 (-0.21, 0.65)	MD 0.22 higher (0.21 lower to 0.65 higher)	Low
Change in Wolf Motor Function Test (functional ability) (12 months follow-up)										

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	CIMT Mean (SD)/ Frequencies (%)	Usual care Mean (SD)/ Frequencies (%)	Mean difference/ Risk Ratio (95% CI)	Absolute Effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
1 Wolf 2006[286]	RCT-single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(e)	(f)	(f)	MD 0.11 (-0.05, 0.27)	MD 0.11 higher (0.05 lower to 0.27 higher)	Moderate
Change in Wolf Motor Function Test (weight) (12 months follow-up)										
1 Wolf 2006[286]	RCT-single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(e)	(f)	(f)	MD 0.67 (-1.51, 2.85)	MD 0.67 higher (1.51 lower to 2.85 higher)	Moderate
Change in Wolf Motor Function Test (grip) (12 months follow-up)										
1 Wolf 2006[286]	RCT-single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(e)	(f)	(f)	MD -2.64 (-6.27, 0.99)	MD 2.64 lower (6.27 lower to 0.99 higher)	Moderate
Functional Independence Measure (post treatment) (Better indicated by higher values)										
5 Dahl 2008[54]; Lin 2007 [154]; Lin 2009[153]; Wu 2007(b)[292] Wu 2007	RCTS- 4 single blinded 1 double blinded	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision(g)	Dahl 2008:107.33(8.8) Lin 2007:113.06(10.55) Lin	Dahl 2008:111.67 (6.49) Lin 2007:105.67(15.85) Lin	MD 2.87 (-0.12, 5.87)	MD 2.87 (0.12 lower to 5.87 higher)	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	CIMT Mean (SD)/ Frequencies (%)	Usual care Mean (SD)/ Frequencies (%)	Mean difference/ Risk Ratio (95% CI)	Absolute Effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
(c)[293]						2009:122.05 (5.6) Wu 2007:104.85 (12.13)	2009:116.65 (8.34) Wu 2007: 100.85 (20.08)			
Functional Independence Measure (total score) (6 months follow-up) (Better indicated by higher values)										
1 Dahl 2008[54]	RCT- single blinded	Serious limitations(d)	No serious inconsistency	No serious indirectness	Serious imprecision(g)	109.56 (8.25)	112.92 (6.75)	MD -3.36 (-8.76 2.04)	MD 3.36 lower (8.76 lower to 2.04 higher)	Low
Functional Independence measure (eating) (post treatment) (Better indicated by higher values)										
1 Dromerick 2000[72]	RCT- single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(g)	6.27 (0.78)	6 (0.92)	MD 0.27 (-0.49, 1.03)	MD 0.27 higher (0.49 lower to 1.03 higher)	Low
Functional Independence measure (grooming) (post treatment) (Better indicated by higher values)										
1 Dromerick 2000[72]	RCT- single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(g)	6.09(0.53)	5.62(0.52)	MD 0.47 (0.01,0.93)	MD 0.47 higher (0.01 to 0.93 higher)	Low
Functional Independence measure (bathing) (post treatment) (Better indicated by higher values)										

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	CIMT Mean (SD)/ Frequencies (%)	Usual care Mean (SD)/ Frequencies (%)	Mean difference/ Risk Ratio (95% CI)	Absolute Effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
1 Dromerick 2000[72]	RCT- single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(g)	5.27 (1.1)	5.25 (0.46)	MD 0.02 (-0.70 ,0.74)	MD 0.02 (0.70 lower to 0.74 higher)	Low
Functional Independence measure (upper extremity dressing) (post treatment) (Better indicated by higher values)										
1 Dromerick 2000[72]	RCT- single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(g)	6 (0.77)	5.25 (0.71)	MD 0.75 (0.10,1.40)	MD 0.75 (0.10 to 1.40 higher)	Low
Fugl-Meyer Assessment (post treatment) (Better indicated by higher values)										
4 Lin 2009[153]; Page 2008[197]; Wu 2007 (a)[291]; Wu 2007 (b)[292]	RCTs- single blinded	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision(l)	Lin 2009: 52.3 (7.17) Page 2008: 48.23 (8.06) Wu 2007 (a): 46.75 (11.58) Wu 2007 (b: 49.54 (12.84))	Lin 2009: 51.25(12.59) Page 2008: 42.42 (12) Wu 2007 (a);: 44.78 (13.08) Wu 2007 (b): 49.38 (10.18)	MD 2.15 (-1.56, 5.86)	MD 2.15 higher (1.56 lower to 5.86 higher)	Low
Fugl-Meyer Assessment (3 weeks follow-up) (Better indicated by higher values)										
1 Van der Lee 1999[270]	RCT- single blinded	No serious limitations	No serious inconsistency	No serious indirectness	No serious imprecision	51.6 (8)	45 (10.6)	MD 6.60 (2.07,11.13)	MD 6.60 higher (2.07 to	High

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	CIMT Mean (SD)/ Frequencies (%)	Usual care Mean (SD)/ Frequencies (%)	Mean difference/ Risk Ratio (95% CI)	Absolute Effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
									11.13 higher)	
Fugl-Meyer Assessment (6 weeks follow-up) (Better indicated by higher values)										
1 Van der Lee 1999[270]	RCT- single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(l)	52.3 (8.3)	46.7 (9.6)	MD 5.60 (1.27 ,9.93)	MD 5.60 higher (1.27 to 9.93 higher)	Moderate
Fugl-Meyer Assessment (1 year follow-up) (Better indicated by higher values)										
1 Van der Lee 1999[270]	RCT- single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision(l)	50.9 (9.9)	45.5 (9.7)	MD 5.4 (0.67, 10.13)	MD 5.4 higher (0.67 to 10.13 higher)	Moderate
Barthel Index (post treatment) (Better indicated by higher values)										
2 Dromerick 2000[72] ; Myint 2008[182]	RCTs- single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision (h)	Dromerick 2000:100 (1.1) Myint 2008: 92.6 (8.5)	Dromerick 2000:98.5 (3.77) Myint 2008: 85.3 (13.6)	MD 3.53 (-1.89 ,8.95)	MD 3.53 higher (1.89 lower to 8.95 higher)	Low
Barthel Index (12 weeks follow-up) (Better indicated by higher values)										
1 Myint 2008[182]	RCT- single blinded	Serious limitations(a	No serious inconsistency	No serious indirectness	Serious imprecision	97.6 (4.2)	93.4 (7.7)	MD 4.2 (0.48, 7.92)	MD 4.2 higher	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	CIMT Mean (SD)/ Frequencies (%)	Usual care Mean (SD)/ Frequencies (%)	Mean difference/ Risk Ratio (95% CI)	Absolute Effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
		)			(i)				(0.48 to 7.92 higher)	
9 hole peg test (post treatment) (Better indicated by higher values)										
1 Myint 2008[182]	RCT- single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Very serious imprecision (j)	16/28 (57.1%)	9/20 (45%)	RR 1.27 (0.71 to 2.27)	121 more per 1000 (from 131 fewer to 572 more)	Very Low
9 hole peg test (3 months follow-up) (Better indicated by higher values)										
1 Myint 2008[182]	RCT- single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision(k)	18/28 (64.2%)	10/20 (50%)	RR 1.29 (0.77 to 2.16)	145 more per 1000 (from 115 fewer to 580 more)	Low
Adverse event (muscle tenderness in the affected arm) (Better indicated by lower values)										
1 Dahl 2008[54]	RCT- single blinded	Serious limitations(d)	No serious inconsistency	No serious indirectness	Very serious imprecision (j)	4/18 (22.2%)	0/12	RR 6.16 (0.36 to 104.90)	145 more per 1000 (from 115 fewer to 580 more)	Very Low

(a) Unclear allocation concealment and unclear allocation concealment
(b) Mean difference did not reach the agreed MID of 12 points.
(c) Unclear randomization and unclear allocation concealment
(d) unclear randomization
(e) Mean difference did not reach the agreed MID of 19 points.

(f) No means (SD) per group were reported by authors.
(g) Mean difference did not reach the agreed MID of 22 points for the total score, 17 points on the motor scale and 3 points for the cognitive scale.
(h) Mean difference did not reach the agreed MID of 6.6 points.
(i) Mean difference did not reach the agreed MID of 9.25 points.
(j) Confidence interval crossed both ends of default MID.
(k) Confidence interval crosses one end of default MID.
(l) Mean difference did not reach agreed MID (10% difference of total score)

Narrative summaries

The following studies are summarised as a narrative because the results were not presented in numerical data that could be included in the GRADE table:

One study [102] randomised a convenient sample of 30 participants into forced-use training (N=15) and standard rehabilitation programme (N=15). The study found that the changes in the forced-use group did not differ from the changes in the standard rehabilitation group for any of the outcome measures (Fugl-Meyer Assessment and Action Research Arm Test). Both groups improved over time (post-treatment - 3 months follow-up), with statistically significant changes in the Fugl-Meyer Assessment (mean score changed from 52 to 57). The trial was unblinded and of a small sample size.

In one study [206], 30 participants were randomly allocated to forced-use therapy and conventional therapy. Participants in the forced-use group had an 85% improvement (baseline = 20.7 (15.49)) in ARAT score, whereas those who received conventional therapy had a 74% improvement (baseline = 16.0 (13.64)) (p=0.20). No significant difference in FIM was observed (data not presented). None of the participants in the forced-use group achieved 6 hours of constraint wearing a day (average time = 2.7 hours/day). Data were presented as graphs and they could not be extracted/ used for meta-analysis. The analysis was not done based on ITT and the study had unclear randomisation and allocation concealment.

13.5.1.2 Economic evidence

Literature review

No relevant economic evaluations comparing constraint induced movement therapy with usual care were identified.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

Looking at resources used in the studies included in the clinical review, the main difference in resources used between intervention and usual care was of the constraint used, with no substantial difference in personnel time. The GDG advised that the cost of constraint was minimal – for example it may involve using bandaging. However, the costs attributable to CIMT will depend on how and when it is offered. If CIMT activities are incorporated as part of the usual rehabilitation, costs may not be substantially higher than usual care; if CIMT is offered in addition to usual rehabilitation care that patients receive, additional costs would be incurred due to additional resource use (for example, staff time).

13.5.1.3 Evidence statements

Clinical evidence statements

Four studies[72,182,197,270] of 159 participants found that patients who received constraint induced movement therapy showed statistically significant improvement in Action Research Arm test compared to patients who received usual care at post-intervention, although it was not of clinical significance (LOW CONFIDENCE IN EFFECT).

One study[270] of 66 participants found that patients who received constraint induced movement therapy showed statistically significant improvement in Action Research Arm test compared to patients who received usual care at 4 weeks follow-up, although it was not of clinical significance (MODERATE CONFIDENCE IN EFFECT).

One study[182] of 66 participants found that patients who received constraint induced movement therapy showed statistically significant improvement in Action Research Arm test compared to patients who received usual care at 12 weeks follow-up (MODERATE CONFIDENCE IN EFFECT).

One study[270] of 66 participants found that patients who received constraint induced movement therapy showed statistically significant improvement in Action Research Arm test compared to patients who received usual care at 10 months follow-up, although it was not of clinical significance (MODERATE CONFIDENCE IN EFFECT).

Three studies[54,254,294] of 115 participants found that patients who received constraint induced movement therapy showed statistically significant improvement in Wolf Motor Function test performance time compared to patients who received usual care at post-intervention, although it was not of clinical significance (LOW CONFIDENCE IN EFFECT).

One study[54] of 30 participants showed that there was no significant difference in performance time of the Wolf Motor Function test between those patients who received constraint induced movement therapy and those who received usual care at 6 months (LOW CONFIDENCE IN EFFECT).

One study [286] of 222 participants showed that patients who received constraint induced movement therapy showed statistically significant improvement in change in the Wolf Motor Function test performance time compared to patients who received usual care at 12 months (HIGH CONFIDENCE IN EFFECT).

Three studies[54,254,294] of 115 participants found that patients who received constraint induced movement therapy showed statistically significant improvement in functional ability of Wolf Motor Function test compared to patients who received usual care at post-intervention, although it was not of clinical significance (LOW CONFIDENCE IN EFFECT).

One study[54] of 30 participants showed no significant difference in the functional ability of the Wolf Motor Function test between those who received constraint induced movement therapy and those who received usual care at 6 months (LOW CONFIDENCE IN EFFECT).

One study[286] of 222 participants showed no significant difference in the change of the Wolf Motor Function test between those who received constraint induced movement therapy and those who received usual care at 12 months for the following scales:

- Functional ability (MODERATE CONFIDENCE IN EFFECT)
- Weight (MODERATE CONFIDENCE IN EFFECT)
- Grip (MODERATE CONFIDENCE IN EFFECT)

Five studies[153,197, 154,292] (Lin 2009, Page 2008, Lin 2007 Wu 2007 (b)) of 160 participants showed that there was no statistically significant difference in the Functional Independence Measure (total score) between those patients who received constraint induced movement therapy and those who received usual care at post-intervention (LOW CONFIDENCE IN EFFECT).

One study[54] of 30 participants showed no significant difference in the Functional Independence Measure (total score) between those who received constraint induced movement therapy and those who received usual care at 6 months (LOW CONFIDENCE IN EFFECT).

One study[72] of 20 participants showed no significant difference in the following scales of the Functional Independence Measure between those who received constraint induced movement therapy and those [197]who received usual care at post intervention:

- eating (LOW CONFIDENCE IN EFFECT)
- Bathing (LOW CONFIDENCE IN EFFECT).

One study[72] of 20 participants showed that patients who received constraint induced movement therapy showed statistically significant improvement in the following scales of the Functional Independence Measure compared to patients who received usual care at post intervention, although these differences were not of clinical significance:

- grooming (LOW CONFIDENCE IN EFFECT)
- upper extremity dressing (LOW CONFIDENCE IN EFFECT

Four studies[153,197,291,292] of 138 participants showed that there was no statistically significant difference in Fugl-Meyer assessment between those patients who received constraint induced movement therapy and those who received usual care at post-intervention (LOW CONFIDENCE IN EFFECT**)**.

One study[270] of 66 participants found that patients who received constraint induced movement therapy showed statistically significant improvement in Fugl-Meyer assessment compared to patients who received usual care at 3 weeks follow-up (HIGH CONFIDENCE IN EFFECT**)**.

One study[270] of 66 participants found that patients who received constraint induced movement therapy showed statistically significant improvement in Fugl-Meyer assessment compared to patients who received usual care at 6 weeks follow-up, although it was not of clinical significance (MODERATE CONFIDENCE IN EFFECT).

One study[270] of 66 participants found that patients who received constraint induced movement therapy showed statistically significant improvement in Fugl-Meyer assessment compared to patients who received usual care at 1 year follow-up although it was not of clinical significance (MODERATE CONFIDENCE IN EFFECT).

Two studies[72,182] of 68 participants showed that there was no statistically significant difference in Barthel Index between those patients who received constraint induced movement therapy and those who received usual care at post intervention (LOW CONFIDENCE IN EFFECT**)**.

One study[182] of 48 participants found that patients who received constraint induced movement therapy showed statistically significant improvement in Barthel Index between those patients who received constraint induced movement therapy and those who received usual care at 12 weeks follow-up, although it was not of clinical significance (LOW CONFIDENCE IN EFFECT).

One study[182] of 48 participants showed that there was no statistically significant difference in Nine – hole Peg test between those patients who received constraint induced movement therapy and those who received usual care at post intervention (VERY LOW CONFIDENCE IN EFFECT).

One study[182] of 48 participants showed that there was no statistically significant difference in Nine – hole Peg test between those patients who received constraint induced movement therapy and those who received usual care at 3 months follow-up (LOW CONFIDENCE IN EFFECT).

One study[54] of 30 participants showed that there was no statistically significant difference in the experience of muscle tenderness in the affected arm between patients who received constraint induced movement therapy and those who received usual care (VERY LOW CONFIDENCE IN EFFECT).

Economic evidence statements

No cost effectiveness evidence was identified.

13.5.2 Recommendations and link to evidence

	95. Consider constraint-induced movement therapy for people with stroke who have movement of 20 degrees of wrist extension and 10 degrees of finger extension. Be aware of potential adverse events (such as falls, low mood and fatigue).
Relative values of different outcomes	The outcomes of interest included the Functional Independence Measure (FIM), Barthel Index, Fugl-Meyer score, Action Research Arm test (ARAT), Wolf Motor Function Test (WMFT) and 9 hole peg test. The 9 hole peg test may be insensitive as it is a measure of fine finger

	movements as well as the ability to reach. Similarly the FIM and Barthel Index as measures of dependence may be unresponsive to changes in upper limb function. The GDG noted that there is no psychometrically robust patient reported outcome measures focussing on upper limb activity. Any adverse event was also included where reported.
Trade-off between clinical benefits and harms	Participants who received constraint induced movement therapy (CIMT) demonstrated a clinically significant improvement in Fugl-Meyer scores at a short term of 3 weeks and in ARAT scores and functional ability of WMFT at 12 weeks follow-up. Although the improvement in performance time of WMFT for those who received CIMT was not of clinical significance at post intervention and at 6 months follow-up, the difference in this outcome became clinically significant between the participants in the CIMT and the usual care groups at 1 year follow-up. Only one study reported adverse events, the experience of muscle tenderness in the affected arm (Dahl, 2008) [54] during constraint induced movement therapy, though its prevalence was not significantly different between the two groups. However the GDG considered there were possible harms associated with this therapy and agreed that when selecting patients for CIMT, attention needs to be made to potential adverse events such as falling and deterioration in mood.
Economic considerations	No cost effectiveness studies were identified for this question. If CIMT activities are incorporated as part of the usual rehabilitation, costs may not be substantially higher than usual care. However, offering CIMT might represent a change in the usual activities that are part of the rehabilitation. The GDG agreed that it is unlikely that CIMT is offered in addition to usual rehabilitation care and therefore no additional costs would be incurred due to additional resource use.
Quality of evidence	The confidence in the effect for the outcomes of Functional Independence Measure, Barthel index, Wolf Motor Function Test, and 9-hole peg test ranged from high to very low due to limitations in study design (unclear allocation concealment and unclear randomisation) and imprecision around the effect estimate. The GDG acknowledged that due to the nature of the intervention it was difficult to recruit people into studies. The mean age of stroke survivors is 73-74 [245]and it was noted that the patients within these studies, with the exception of the Wu study 2007 (b) [292], were relatively young for a stroke population and are likely to reflect those who are admitted into specialist rehabilitation units. In patients with movement of 20 degrees wrist and 10 degrees in fingers Constraint Induced Movement Therapy with repetitive task practice may be of benefit for patients both early (2 weeks after onset) and late after stroke.
Other considerations	The GDG agreed that the active element of constraint therapy is the amount of practice performed by the weak arm and this needs to be carefully structured and tailored to the individual patient needs. The GDG were unsure what value patients place on small improvements in upper limb function. Whilst this type of intervention may not be suitable or tolerated by some patients, the GDG agreed that it is an intervention that tends to be used with those patients who are highly motivated to get their movements back and it is these who would value this type of intervention most.

13.6 Shoulder pain

There was a lack of direct evidence for the treatment of shoulder pain. Therefore recommendations in this section were based on modified Delphi consensus statements derived from published national and international guidance. This section of the Delphi survey was aimed at those Delphi panel members who felt they had the relevant experience to comment on shoulder pain. Other Delphi panel members could 'opt out' of this section. Response rates were therefore lower in this section. Below we provide tables of statements that reached consensus and statements that did not reach consensus and give a summary of how they were used to draw up the recommendations. For details on the process and methodology used for the modified Delphi survey see Appendix F.

13.6.1 How should people with shoulder pain after stroke be managed to reduce pain?

Population	Adults and young people 16 or older who have had a stroke and have symptoms of shoulder pain
Components	• Assessment • Pain management • FES • Physical therapies
Outcomes	• Mobility • Function • pain

13.6.2 Delphi statements where consensus was achieved

Table 105: Table of consensus statements, results and comments (percentage in the results column indicates the overall rate of responders who 'strongly agreed' with a statement and 'amount of comments' in the final column refers to rate of responders who used the open ended comments boxes, i.e. No. people commented / No. people who responded to the statement)

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
	Information should be provided by the healthcare professional on how to prevent pain/trauma to the shoulder.	77.6	7/49 (14%) panel members commented Most panel members who commented on this question **queried who to give the information to** (patient, carer, other staff) and **under which conditions** (if there is weakness in the shoulder). It was stated in one comment that there was **no information available** on this topic.
1.	When managing shoulder pain the following treatments should be considered: • Positioning	70.7	In round 2 - 23/49 (47%) panel members commented; 13/42(31%) in round 3 **None of the other treatment**

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
			options gained consensus the options were: • Arms slings, • Shoulder support, • High intensity transcutaneous nerve stimulation, and • Functional Electrical Stimulation • Analgesics • Physical therapies • Strapping Comments were divided: • A number of panel members stated that shoulder pain has to be **treated** in a flexible manner and **according to individual needs**. • Some stated that treatment should be **evidence based**. • Others stated that the **evidence** for most of the options was **poor**

13.6.3 Delphi statement where consensus was not reached

Table 106: Table of 'non-consensus' statements with qualitative themes of panel comments

Number	Statement	Results %	Amount and content of panel comments – or themes
1.	The person who has had a stroke should be assessed for shoulder pain	63.6	In round 2 - 13/48 (27%) panel members commented; 7/42(17%) in round 3 There was a **general opinion** that this should be **easily ascertained** and therefore a full **assessment** is **not needed.**
2.	There is a need for an algorithm to assess and treat shoulder pain	31.0	In round 2 - 23/49 (47%) panel members commented; 13/42(31%) in round 3 Some comments were made that there are **algorithms** already **in existence**. Others commented that the **evidence** for treatments was **poor** and therefore there is not enough information to create an algorithm. There were also comments that **this**

Number	Statement	Results %	Amount and content of panel comments – or themes
			would be useful.

13.6.4 Recommendations and links to Delphi consensus survey

Statements	32. Information should be provided by the healthcare professional on how to prevent pain/trauma to the shoulder. 33. When managing shoulder pain the following treatments should be When managing shoulder pain the following treatments should be considered: • Positioning
Recommendation	**96. Provide information for people with stroke and their families and carers on how to prevent pain or trauma to the shoulder if they are at risk of developing shoulder pain (for example, if they have upper limb weakness and spasticity).** **97. Manage shoulder pain after stroke using appropriate positioning and other treatments according to each person's need.** **98. For guidance on managing neuropathic pain follow Neuropathic pain (NICE clinical guideline 96).**
Economic considerations	There is a minor cost of staff time associated with the provision of information. However the GDG considered these to be largely offset by the benefits.
Other considerations	The GDG agreed this was a common problem amongst people after stroke and that prevention should be highlighted. However, the means of preventing shoulder pain is not universally agreed and this may be due, to the large array of identified causes, including spasticity, thalamic (central) pain, complex regional pain syndromes (CRPS), (for example: shoulder-hand syndrome), fracture and soft-tissue problems. It is generally agreed that one of the major causes of injuring the shoulder is poor manual handling and support of the at-risk arm by health professionals, carers, or the patient themselves. In the survey consensus was reached only for providing information to prevent shoulder pain. The GDG clarified this statement by indicating the people likely to develop shoulder pain were those with changes in tone or power in their arms. Algorithms and assessments did not reach consensus in the Delphi and the GDG discussed the pros and cons of including this in a list of assessments routinely carried out. It was felt that asking people who display discomfort when moving their arms would be sufficient in the majority of cases. Whilst there was consensus that positioning the shoulder may help to alleviate symptoms, overall the view from the survey showed there was no evidence base to recommend any particular treatment. The GDG

	agreed this was an area where further research was needed to assess the effectiveness of the various management strategies currently used, and agreed that a research recommendation be included in the guideline. The GDG were surprised that there was no agreement about the use of a simple treatment such as analgesics to alleviate pain. The group agreed that whilst it was not possible to make a recommendation, health professionals should consider other treatments according to individual need. The GDG acknowledged that a varied range of therapies were currently being used in practice that include: upper limb support including slings and orthotics, strapping of the shoulder, range of motion exercises, ultrasound, electrical stimulation, steroid and botulinum toxin injections, acupuncture and massage therapy. The use of shoulder slings may be associated with some risks, including holding the limb in a poor position that is likely to cause soft tissue contracture, inhibiting use of a recovering limb, and have an adverse effect on symmetry and balance, making falls more likely.

13.7 Repetitive task training

Rehabilitation is integral to the care pathway after stroke. However the optimum components of physical rehabilitation are uncertain. Repetitive task training promotes the repetition of motor movement related to purposeful tasks. This might for example include reaching for a cup or combing hair. The focus is generally on the impaired limb and is one approach to increase the amount of physical rehabilitation.

13.7.1 Evidence review: In people after stroke what is the clinical and cost effectiveness of repetitive task training versus usual care on improving function and reducing disability?

Clinical Methodological Introduction	
Population	Adults and young people 16 or older who have had a stroke
Intervention	• Repetitive task training • Lower limb functional tasks and / or • Upper limb functional tasks
Comparison	Usual care
Outcomes	<u>Lower limb</u> • Any timed walk; 6 minute walk test, 5 metre, 10 metre timed walk • Change in walking distance • Rivermead mobility index <u>Upper limb</u> Arm: • Fugl-Meyer Assessment, • Action Research Arm Test (ARAT) Hand: • Any peg hole test, • Frenchay Arm Test, • Motor Assessment Scale (MAS)

13.7.1.1 Clinical evidence

Searches were conducted for systematic reviews and RCTs comparing the clinical effectiveness of repetitive task training with usual care to improve function and reduce disability for adults and young people 16 or older who have had a stroke. Only studies with a minimum sample size of 20 participants (10 in each arm) were selected. Five RCTs were identified.

Table 107 summarises the population, intervention, comparison and outcomes for each of the studies.

Table 107: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix H.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Blennerhassett, 2004[27]	Inpatients with a primary diagnosis of stroke and who are able to walk 10 metres with supervision (with or without walking aids)	Lower limb training: therapist-assisted functional tasks included sit to stand, step ups, obstacle course, plus stretching/strengthening exercise, and some endurance training (stationary, bikes and treadmill) for 1 hour/day, 5 days/week for 4 weeks. (N=15)	Therapist-assisted functional tasks to improve reach and grasp, hand-eye coordination, stretching and strengthening for 1 hour/day, 5 days/week for 4 weeks. (N=15)	• Motor assessment Scale (MAS)-hand • 6-minute walk test (m) • Time up and go test (sec)
Higgins, 2006[111]	Patients with a first or recurrent stroke (less than 1 year post-stroke at study entry); who had the ability to walk 10m independently using an aide or orthosis with/without supervision.	Arm training: 90-minute per session (total 18 sessions) 3 times a week for 6 weeks with a therapist to repetitively perform tasks that the patients found difficult. Tasks were changed or their level of difficulty was increased when patients maximised their performance. (N=47)	18 sessions of walking intervention consisted of 10 functional tasks 3 times a week for 6 weeks. (N=44)	• 9 hole peg test
Kwakkel, 1999[140]	Severely disabled patients with primary first-ever stroke (within 14 days after stroke onset); with an inability to walk at first assessment.	Upper limb training: functional exercises that facilitated forced arm and hand activity. (N=33) Lower limb training: emphasis on achieving stability and improving gait velocity (N=31). Both interventions were assisted by therapists for 30 minutes, 5 days/week for a total of 20 weeks, plus 1.5hour/week activities of daily living training by an occupational therapist.	Arm and leg were immobilised with an inflatable pressure splint (30min, 5 days/week). (N=37)	• Action Research Arm test (ARAT) • 10 metre timed walking test: comfortable and maximum walking speed (m/sec)

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Salbach, 2004[229]	Patients with walking deficit within one year of a first or recurrent stroke; able to walk independently using an aide or orthosis with/without supervision.	Lower limb training: 10 walking-related tasks (total 18 sessions) supervised by a physical or occupational therapist, for 3 times/week for 6 weeks, in rehabilitation or hospital setting. (N=44)	Functional upper extremity tasks (total 18 sessions/ 3 times per week for 6 weeks) that were done while sitting and patients were recommended to practise at home. (N=47)	• 6 minute walk test (m) • 5 metre timed walk: comfortable and maximum walking speed (m/s) • Timed up & go test (sec)
Winstein, 2004[285]	Patients with recent first time stroke (2 to 35 days post onset) from infarction in the anterior circulation.	Upper limb task functional training for 1 hour/day, 5 days/week for 4 weeks: repetitive practice of tasks within the level of available voluntary motion. All tasks are designed to be standard, repeatable, and to have some functional goal (for example pointing, grasping and stirring). (N=22)	Muscle facilitation exercises, neuromuscular electric stimulation applied primarily for shoulder subluxation, stretching exercises, activities of daily living (self-care where the upper limb was used as an assist) and caregiver training. (N=21)	Fugl-Meyer Assessment: • range of motion • pain • sensory • motor function

Comparison: lower limb training (repetitive task or functional) versus usual care

Table 108: Lower limb training (repetitive task or functional) versus usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Lower limb training Mean (SD) or median (IQR)	Usual care Mean (SD) or median (IQR)	Mean difference(95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
6 minute walk test (m) (post treatment effect) (Better indicated by higher values)										
Blennerhassett 2004[27]; Salbach 2004[229]	RCTs single-blinded	Serious limitations (a,b)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	Blennerhassett: 404 (101) Salbach: 249 (136)	Blennerhassett: 288 (124) Salbach: 209 (132)	64.09 (18.52, 109.65)	MD 64.09 higher (18.52 to 109.65 higher)	Low
6 minute walk test (m) (6 months follow-up) (Better indicated by higher values)										
Blennerhassett 2004[27]	RCT single-blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(c)	416 (171)	313 (154)	103 (-13.46, 219.46)	MD 103 higher (13.46 lower to 219.46 higher)	Low
Timed up and go test (sec) (post treatment effect) (Better indicated by lower values)										
Blennerhassett 2004[27]; Salbach 2004[229]	RCTs single-blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(d)	Blennerhassett: 11.5 (3.8) Salbach:	Blennerhassett: 19.1	-6.23 (-12.22, -0.25)	MD 6.23 lower (12.22low	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Lower limb training Mean (SD) or median (IQR)	Usual care Mean (SD) or median (IQR)	Mean difference(95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
						23.2 (20.6)	(14.4) Salbach: 27.1 (27.1)		er to 0.25 lower)	
Timed up and go test (sec) (6 months follow-up) (Better indicated by lower values)										
Blennerhassett 2004[27]	RCT single-blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(d)	10.8 (4.5)	21.3 (30.3)	-10.50 (-26.0, 5.0)	MD 10.50 lower (26.0 lower to 5.0 higher)	Low
5 and 10 metre timed walk: comfortable speed (m/sec) (post treatment effect) (Better indicated by higher values)										
Kwakkel 1999[140] Salbach 2004[229]	RCTs single-blinded	Serious limitations (a,b)	No serious inconsistency	No serious indirectness	No serious imprecision	Kwakkel: 0.65 (0.46) Salbach: 0.78 (0.40)	Kwakkel:0.37 (0.41) Salbach: 0.64 (0.37)	0.48 (0.16, 0.79)	SMD 0.48 higher (0.16 higher to 0.79 higher)	Moderate
5 and 10 metre timed walk: maximum speed (m/sec) (post treatment effect) (Better indicated by higher values)										
Kwakkel 1999[140] Salbach 2004[229]	RCTs single-blinded	Serious limitations (a,b)	No serious inconsistency	No serious indirectness	No serious imprecision	Kwakkel: 0.88 (0.66) Salbach:	Kwakkel: 0.52 (0.58)	0.45 (0.13, 0.77)	SMD 0.45 higher (0.13 higher to	Moderate

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Lower limb training Mean (SD) or median (IQR)	Usual care Mean (SD) or median (IQR)	Mean difference(95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
						0.99 (0.56)	Salbach: 0.80 (0.49)		0.77 higher)	
10 metre timed walking: comfortable speed (m/sec) (6 ½ months follow-up) (Better indicated by higher values)										
Kwakkel 1999[140]	RCT single-blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision (e)	0.63 (0.47)	0.44 (0.44)	0.19 (-0.03, 0.41)	MD 0.19 higher (0.03 lower to 0.41 higher)	Low
10 metre timed walking: maximum speed (m/sec) (6 ½ months follow-up) (Better indicated by higher values)										
Kwakkel 1999[140]	RCT single-blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision (e)	0.85 (0.65)	0.57 (0.60)	0.28 (-0.02, 0.58)	MD 0.28 higher (0.02 lower to 0.58 higher)	Low

[(a)] Unclear allocation concealment
[(b)] 7 patients withdrawn from trial; 4 patients with missing baseline/follow-up data (Salbach 2004).
[(c)] Confidence interval crossed the lower limit of agreed MID (28m)
[(d)] Mean difference did not reach the agreed MID of 10 sec.
[(e)] Confidence intervals crossed one end of default MID.

Comparison: Upper limb training (repetitive task or functional) versus usual care

Table 109: Upper limb training (repetitive task or functional) versus usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Upper limb training Mean (SD)/median (IQR)	Usual care Mean (SD)/ median (IQR)	Mean difference (95% CI)	Absolute effect / Mean Difference (MD) (95% CI) or p-value	Confidence (in effect)
9 hole peg test (1 ½ months follow-up) (Better indicated by higher values)										
Higgins 2006[111]	RCT single-blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	No serious imprecision	1 (1)	1(1)	0.00 (-0.41, 0.41)	MD 0.00 (0.41 lower to 0.41 higher)	Moderate
Motor assessment scale (MAS) – hand (post treatment effect) (Better indicated by higher values)										
Blennerhassett 2004[27]	RCT single-blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	(b)	6 (5-6)	6 (5-6)	(c)	(d)	Moderate (b)
Motor assessment scale (MAS) – hand (6 months follow-up) (Better indicated by higher values)										
Blennerhassett 2004[27]	RCT single-blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	(b)	6 (4.2-6.0)	6 (3-6)	(c)	(d)	Moderate (b)
Action Research Arm test (post treatment effect) (Better indicated by higher values)										
Kwakkel 1999[140]	RCT single-blinded	Serious limitations(e)	No serious inconsistency	No serious indirectness	(b)	6 (4.2-6.0)	6 (3-6)	(c)	p<0.01 (e)	Moderate (b)

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Upper limb training Mean (SD)/median (IQR)	Usual care Mean (SD)/ median (IQR)	Mean difference (95% CI)	Absolute effect / Mean Difference (MD) (95% CI) or p-value	Confidence (in effect)
Action Research Arm test (6 ½ months follow-up) (Better indicated by higher values)										
Kwakkel 1999[140]	RCT single-blinded	Serious limitations(c)	No serious inconsistency	No serious indirectness	(b)	4 (0-38)	0 (0-2.25)	(c)	p<0.001(e)	Moderate (b)
Fugl-Meyer Assessment - range of motion (post treatment effect) (Better indicated by higher values)										
Winstein 2004[285]	RCT - unblinded	Serious limitations(f)	No serious inconsistency	No serious indirectness	Very serious imprecision (g)	-1.9 (2.02)	-0.6 (1.93)	-1.30 (-2.48, -0.12)	MD 1.30 lower (2.48 lower to 0.12 lower)	Very low
Fugl-Meyer Assessment - pain (post treatment effect) (Better indicated by higher values)										
Winstein 2004[285]	RCT - unblinded	Serious limitations(f)	No serious inconsistency	No serious indirectness	Very serious imprecision (g)	-1.6 (2.8)	-0.6 (1.79)	-1.00 (-2.40, 0.40)	MD 1.00 lower (2.40 lower to 0.40 higher)	Very low
Fugl-Meyer Assessment - sensory (post treatment effects) (Better indicated by higher values)										
Winstein 2004[285]	RCT - unblinded	Serious limitations(f)	No serious inconsistency	No serious indirectness	Very serious imprecision (g)	0.75 (2.99)	0.75 (1.33)	0.00 (-1.37, 1.37)	MD 0.00 (1.37 lower to 1.37 higher)	Very low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Upper limb training Mean (SD)/median (IQR)	Usual care Mean (SD)/ median (IQR)	Mean difference (95% CI)	Absolute effect / Mean Difference (MD) (95% CI) or p-value	Confidence (in effect)
Fugl-Meyer Assessment – motor function (post treatment effect) (Better indicated by higher values)										
Winstein 2004[285]	RCT - unblinded	Serious limitations(f)	No serious inconsistency	No serious indirectness	Serious imprecision (h)	16.5 (13.74)	9.05 (7.6)	7.45 (0.85, 14.05)	MD 7.45 higher (0.85 lower to 14.05 higher)	Low
Fugl-Meyer Assessment – range of motion (9 months follow-up) (Better indicated by higher values)										
Winstein 2004[285]	RCT - unblinded	Serious limitations(f , i)	No serious inconsistency	No serious indirectness	Very serious imprecision (g)	-0.46 (2.76)	-0.33 (1.45)	-0.13 (-1.44, 1.18)	MD 0.13 lower (1.44 lower to 1.18 higher)	Very low
Fugl-Meyer Assessment - pain (9 months follow-up) (Better indicated by higher values)										
Winstein 2004[285]	RCT - unblinded	Serious limitations(f , i)	No serious inconsistency	No serious indirectness	Very serious imprecision (g)	-1.23 (2.42)	-1.00 (2.88)	-0.23 (-1.82, 1.36)	MD 0.23 lower (1.82 lower to 1.36 higher)	Very low
Fugl-Meyer Assessment - sensory (9 months follow-up) (Better indicated by higher values)										
Winstein 2004[285]	RCT - unblinded	Serious limitations(f	No serious inconsistency	No serious indirectness	Very serious imprecision	0.69 (2.36)	0.07 (1.03)	0.62 (-0.46, 1.70)	MD 0.62 higher	Very low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Upper limb training Mean (SD)/median (IQR)	Usual care Mean (SD)/ median (IQR)	Mean difference (95% CI)	Absolute effect / Mean Difference (MD) (95% CI) or p-value	Confidence (in effect)
		, i)			(g)				(0.46 lower to 1.70 higher)	
Fugl-Meyer Assessment – motor function (9 months follow-up) (Better indicated by higher values)										
Winstein 2004[285]	RCT - unblinded	Serious limitations(f , i)	No serious inconsistency	No serious indirectness	Very serious imprecision (g)	5.77 (4.49)	8.33 (11.26)	-2.56 (-7.73, 2.61)	MD 2.56 lower (7.73 lower to 2.56 higher)	Very low

[a] Unclear allocation concealment (Blennerhassett 2004)
[b] Imprecision could not be assessed as results were presented in median and its interquartile range and could not be meta-analysed.
[c] Results were presented as median (IQR) and couldn't estimate relative/absolute effect.
[d] Authors reported that there was no significant difference on the MAS (hand) between the lower limb training group and the usual group.
[e] P value as reported by authors
[f] Study was not blinded, unclear randomization and inadequate allocation concealment.
[g] Confidence interval crossed both ends of agreed MID (difference by 10%).
[h] Mean difference and its confidence intervals did not reach the agreed MID (difference by 10% of the scale).
[i] High rate of loss to follow-up at 9 months (7 in the functional task group and 5 in standard care group).

13.7.1.2 Economic evidence

Literature review

No relevant economic evaluations comparing repetitive task training with usual care were identified.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

In the RCTs included in the clinical review a substantial difference in terms of personnel time was not seen between usual care and repetitive task training. Some negligible costs would be linked with the use of cards that patients were asked to manipulate (for example, in Higgins 2002[111]). However, the GDG noted that this was due to the studies 'matching' the intensity of input; in real life it was expected that repetitive task training might involve some additional therapy time or that carers would be trained to assist.

13.7.1.3 Evidence statements

Clinical evidence statements

Two studies[27,229] of 121 participants showed that there was a statistically significant improvement in locomotor performance assessed by the 6 minute walk test (m) in the group that received mobility/ lower limb training, compared with the usual care group at the end of the treatment (LOW CONFIDENCE IN EFFECT).

One study[27] of 30 participants showed no significant difference in locomotor performance assessed by the 6 minute walk test (m) between the mobility/ lower limb training group and the usual care group at 6 months follow-up (LOW CONFIDENCE IN EFFECT).

Two studies[27,229] of 121 participants showed a statistically significant improvement in the Timed Up and Go Test (sec) for the group received the lower limb training compared to the usual care group at the end of the treatment (LOW CONFIDENCE IN EFFECT).

One study[27] of 30 participants showed no significant difference in locomotor performance assessed by the Timed Up and Go Test (sec) between the mobility/ lower limb training group and the usual care group at 6 months follow-up (LOW CONFIDENCE IN EFFECT).

Two studies[140,229] of 159 participants found a significant difference in comfortable and maximum walking speed measured by 5 and 10 m timed walk (m/sec) between those who received mobility/lower limb training and the usual care group at the end of the treatment (MODERATE CONFIDENCE IN EFFECT).

One study[140] of 68 participants showed no significant difference in comfortable and maximum walking speed measured by 5 and 10 m timed walk (m/sec) between those who received mobility/lower limb training and the usual care group at 6 ½ months follow-up (LOW CONFIDENCE IN EFFECT).

One study[111] of 91 participants found no significant difference in the 9 hole peg test scores between the arm training group and the usual care group at the end of the treatment (MODERATE CONFIDENCE IN EFFECT).

One study[285] of 33 participants showed that the standard care group was associated with a statistically significant improvement in the Fugl-Meyer assessment (range of motion), compared with those who received functional task arm training at the end of treatment (VERY LOW CONFIDENCE IN EFFECT).

One study[285] of 33 participants showed no significant difference between the functional task arm training group and the usual care group at the end of the treatment on the following outcomes:

- Fugl-Meyer assessment (pain) (VERY LOW CONFIDENCE IN EFFECT)
- Fugl-Meyer assessment (sensory) (VERY LOW CONFIDENCE IN EFFECT)

One study[285] of 33 participants showed that the functional task arm training group was associated with a statistically significant improvement in the Fugl-Meyer assessment (motor function) compared with those who received usual care at the end of the treatment (LOW CONFIDENCE IN EFFECT).

One study[285] of 33 participants found no significant difference between the functional task arm training group and the usual care group at 9 months follow-up on the following outcomes:

- Fugl-Meyer assessment (range of motion (VERY LOW CONFIDENCE IN EFFECT)
- Fugl-Meyer assessment (pain) (VERY LOW CONFIDENCE IN EFFECT)
- Fugl-Meyer assessment (sensory) (VERY LOW CONFIDENCE IN EFFECT)
- Fugl-Meyer assessment (motor function) (VERY LOW CONFIDENCE IN EFFECT)

Evidence statements could not be produced for the following outcome(s) as results were not presented in a way that enabled the size of the intervention's effect to be estimated:

- Action research arm test (upper limb training versus standard care)[140]
- Motor assessment scale (hand) (upper limb training versus standard care)[27]

Economic evidence statements

No cost effectiveness evidence was identified.

13.7.2 Recommendations and link to evidence

Recommendations:	**99. Offer people repetitive task training after stroke on a range of tasks for upper limb weakness (such as reaching, grasping, pointing, moving and manipulating objects in functional tasks) and lower limb weakness (such as sit-to-stand transfers, walking and using stairs).**
Relative values of different outcomes	All the repetitive tasks considered in the review comprised of circuit type tasks for upper and lower limb. Other types of repetitive task such as dressing practice or treadmill were not identified by the search. The outcomes of interest for the lower limb were any timed walk, change in walking distance and Rivermead Mobility Index. As there were a variety of different timed walk measures the GDG requested that the results be presented together as no greater emphasis would be placed on one over another. The GDG agreed to use the following minimal important differences (MIDs) published in the literature for the following outcomes reported; 20 cm/sec for the walking speed, 12 and 17 points for the affected dominant and non-dominant sides respectively when assessing the outcome of Action Research Arm (ARAT) and difference by 10% of the total scale for the Fugl-Meyer assessment (FMA) (please refer to **Table 5** in the methodology chapter for more details on the published sources

	of the agreed minimal important differences).
Trade-off between clinical benefits and harms	The GDG agreed there were no significant harms associated with these interventions. The consensus of the GDG was that repeated practice for both upper and lower limb functions was likely to be beneficial in terms of patients' quality of life and social inclusion.
Economic considerations	No relevant cost effectiveness evidence was identified. The clinical studies included in the review did not indicate a difference in resource use between repetitive task training and usual care; however, it was considered that in reality there may be some additional personnel time, therefore costs associated with repetitive task training. The GDG considered these costs to be offset by the benefits.
Quality of evidence	The GDG noted that two of the studies included in the review (Salbach, 2004 and Higgins 2002) are the same study with one reporting upper extremity intervention results and the other mobility. Two studies showed a significant improvement in the 6-minute walk test (Blennerhassett, 2004 and Salbach, 2005[27,229]) and two in the timed metres walks (Kwakkel, 1999 and Salbach, 2004 [140,229]). The GDG noted that this improvement was found at the end of the study (post treatment effect) but not at 6 months follow-up (Kwakkel, 1999[140]), however it would usually be expected that once patients were walking this would be maintained. The lower limb outcomes were graded between low and moderate due to study limitations and imprecision around the effect estimate. The Winstein (2004) study demonstrated that functional task arm training was associated with a significant improvement with motor function compared to usual care group at the end of treatment. Confidence in the results for these outcomes was graded as very low due to limitations in study design (inadequate allocation concealment and randomisation) and the effect estimate not reaching the minimal important difference of 10% of the scale. However this improvement in the motor ability outcomes was not preserved at 9 months follow-up. It was not possible to estimate the size of effect of the upper limb interventions within the Kwakkel and Blennerhassett studies as results were presented only as medians (IQR).
Other considerations	The GDG considered that the interventions used for upper limb which included tasks such as manipulating playing cards and handwriting are not representative of usual therapeutic interventions. However the GDG believed such tasks are important in terms of enabling the patient to undertake activities themselves and promoting participation and self-esteem. The GDG agreed that although useful for some patients these are high level tasks. The GDG agreed that the trials included those people who already had some upper limb function, and that this is the group who are most likely to benefit from the interventions.

13.8 Walking therapies: treadmill and treadmill with body weight support

There are two types of treadmill training that are currently used to assist with the re-education of gait following a stroke. The first is a conventional treadmill that requires the stroke survivor to mobilise bearing the full weight of their body. The second is a treadmill with body weight support that allows the stroke survivor to mobilise without requiring that they carry the full weight of their body. As they become stronger they are able to gradually reduce the body weight support. The use of treadmill training both with and without body weight support has been shown to assist with the

re- education of gait following stroke, as an adjunct to conventional physiotherapy. It has not been demonstrated to be of benefit instead of routine physiotherapy intervention.

13.8.1 Evidence review: In people after stroke what is the clinical and cost-effectiveness of all treadmill versus usual care on improving walking?

13.8.2 Evidence review: In people after stroke who can walk, what is the clinical and cost effectiveness of treadmill plus body support versus treadmill only on improving walking?

Clinical Methodological Introduction	
Population	Adults and young people 16 or older who have had a stroke
Intervention	Any treadmill training (with or without body support)
Comparison	• Usual care (other physiotherapy) • Treadmill without body support
Outcomes	• Walking speeds (5 m/ 10 m / 30 m) • Any timed walk • Walking endurance • Functional Independence Measure (FIM) • Barthel Index • Rivermead Mobility Index

13.8.2.1 Clinical evidence review

Searches were conducted for systematic reviews (of randomized controlled trials (RCTs) and cohort studies) and RCTs that compared the effectiveness of all treadmill therapies with usual care to improve walking for adults and young people 16 or older who have had a stroke. Only studies with a minimum sample size of 20 participants (10 in each arm) and including at least 50% of participants with stroke were selected. Sixteen (16) RCTs were identified. One study [190] included treadmill training exercise with body support compared to usual care and three studies [15,115,272] compared treadmill training exercise with body support with treadmill training exercise without body support. All the other studies compared treadmill without body weight support versus usual care. **Table 110** summarises the population, intervention, comparison and outcomes for each of the studies included in the clinical evidence review.

Table 110: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix H.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Barbeau 2003[15]	Stroke patients (onset <6 months ago) referred in a hospital for physical rehabilitation who couldn't walk in a normal gait pattern.	Treadmill training with body while an overhead harness supported a percentage of their body weight with the assistance of 1 or 2 therapists as needed. Patients were provided up to 40% body weight support	Treadmill training without a body support with the assistance of 1 or 2 therapists as needed (N=50).	• Proportion of participants achieved over ground walking speed over 0.2 m/s • Proportion of participants achieved over ground walking endurance over 20 m

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
		at the beginning of the training, and that percentage was progressively decreased as their ability to walk improved (N=50)		
Duncan 2011[73]	Inpatients who had stroke within 45 days before study entry and the ability to undergo randomisation within 2 months after stroke; patients experienced residual paresis in the leg but were able to walk 3m with assistance.	Early treadmill training with partial body weight support and manual assistance as needed for 20-30 minutes at 3.2 km per hour, followed by a progressive program of walking over ground for 15 minutes. Study duration: 12-16 weeks. (N=139)	Home exercise program – task-specific walking program, managed by a physical therapist in the home, with the goals of enhancing flexibility, range of motion in joints, strength of arms and legs, coordination, and static and dynamic balance. (N=126)	• 10 metre walk time (m/sec) • 6 minute walk test (m)
Eich, 2004[74]	Patients with first-time stroke (<6weeks of stroke onset) referred to inpatient rehabilitation centre. Follow-up time= 3 months	Treadmill training with no body weight support for 30 minutes and other individual physiotherapy for 30 minutes for 6 weeks (N=25).	Usual care included 60 minutes of individual physiotherapy daily for 6 weeks (N=25).	• 10 metre timed walk (m/sec) • 6 minute walk test (m) • Rivermead Motor Assessment Score
Franceschini, 2009[86]	Patients with sub-acute stroke (<6 weeks of stroke onset) who were unable to walk. Follow-up time = 6 months.	Treadmill training with body weight support for 20 minutes followed by 40 minutes of conventional training for 5 times a week for 20 sessions. The training should have been completed within 5 weeks of inclusion in the study. (N=52)	Usual care included 20 sessions of conventional treatment (consisting of over ground gait training) of 60 minutes each session. 5 times per week for 20 sessions, which should have been completed within 5 weeks of inclusion in the study. (N=50)	• 10 metre timed walk test (m/sec) • 6 minute walk test (m) • Barthel Index
Kosak, 2000[138]	Patients admitted to inpatient stroke rehabilitation unit. (time since	Partial body weight support treadmill training (with overhead motorised hoist attached to a	Aggressive bracing assisted walking (using hemi-bar and knee-ankle-foot orthosis if necessary)	• Walking speed (2-minute test period) (m/minute) • Walking endurance (m)

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
	stroke (mean days); 39 for the intervention group and 40 for the control group).The sample included some severely affected patients with hemiparesis-hemisensory-hemianopic visual deficits	parachute-type body harness; assisted by physical therapist and physical therapy-aide) for up to 45 minutes as tolerated, and 45 minutes of traditional physical therapy 5 days a week. (N=22)	for up to 45 minutes as tolerated, and 45 minutes of traditional physical therapy 5 days a week. (N=34)	
Kuys 2011[139]	Patients with first time stroke (time since stroke - mean days 52 for the intervention group and 48 for the control group) Patients were followed up at 6 and 18 weeks post intervention.	Treadmill training for 30 minutes (excluding rests), three times a week for 6 weeks, at an intensity of 40-60% heart rate reserve or a Borg Rating of Perceived Exertion of 11-14. Also received usual physiotherapy of approximately one hour per day. (N=15)	Usual physiotherapy of approximately one hour per day of comprehensive therapy using a task oriented approach targeting impairments and activity limitations specific to each participant. (N=15)	• Walking endurance (m) • Comfortable walking speed (m/sec) • Fast walking speed (m/sec)
Langhammer, 2010[143]	Patients with stroke at a private rehabilitation centre. (<8 weeks of stroke onset) No follow-up.	Treadmill training exercise with no body support for up to 30 minutes for five days per week. The treadmill had hand railings to hold on to, otherwise there were no safety precautions (N =21).	Outdoor walking exercise included walking at a comfortable speed five days a week with the use of ordinary assistive devices when necessary. (N =18)	• 6 minute walk test (m) • 10 metre timed walk (m/sec)
Laufer,2001[147]	First stroke patients (onset of stroke <=90 day) with an ability to walk on treadmill at a speed of at least 0.2km/hr. with minimal to moderate assistance for 2 minutes without rest. No follow-up.	Treadmill training exercise consisted of ambulating on a motor-driven treadmill which was adjusted to the subject's comfortable walking speed for 5 sessions a week for 3 weeks. Actual walking time during training sessions included 4 min per day the first week, 6 min per day in 2nd week and 8min per day in 3rd week. (N=13)	Floor walking exercise consisted of ambulating on floor surface at a comfortable speed using walking aids, assistance, and resting periods as needed. Actual walking time included 4 min per day the first week, 6 min per day in 2nd week and 8min per day in 3rd week. (N=12).	• 10 metre timed walk (m/sec)

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Luft, 2008[160]	Patients with chronic hemiparetic gait (>=6 months after their first stroke). No follow-up.	Treadmill training exercise included three exercises of 40 minutes each per week at an aerobic intensity of 60% of heart rate reserve, for 6 months. (N =57)	Usual care included 13 supervised traditional stretching movements (actively if possible or passively) on a raised mat table with a therapist's assistance for 6 months (N =56)	• 10 metre timed walk (m/sec) • 6 minutes timed walk (m)
Nilsson, 2001[190]	Patients with a first stroke (<8 weeks from onset of stroke) with residual hemiparesis after stroke. Follow-up time = 10 months.	Treadmill training with body weight support was provided for 30 minutes for five days a week. The body weight support was gradually reduced as fast as possible as the goal was to attain walking on the treadmill with full weight-bearing. (N=36)	Usual care included individual walking training by a physiotherapist for 30 minutes five days a week. (N =37)	• FIM • 10 metre timed walk (m/sec)
Olawale 2011[193]	Patients (from an African population) with chronic stroke (3-24 months) in an outpatient stroke rehabilitation unit in a tertiary hospital; who were able to walk 10 m independently with or without a walking aid.	Treadmill walking training and conventional physiotherapy for 12 weeks. (N=20)	Group 1: Over ground walking exercise and conventional physiotherapy for 12 weeks (N=20) Group 2: Usual care - conventional physiotherapy only for 12 weeks (N=20)	• 10 metre timed walk (m/sec) • 6 minute walk test (m)
Pohl, 2002[208]	Patients with hemiparesis caused by stroke, admitted to a post stroke inpatient rehabilitation centre (>4 weeks post stroke). No follow-up.	Structured speed-dependent treadmill training (STT); 12 x 30 min of STT, 8 x 45 min conventional physiotherapy (gait training allowed) in total 12 hours of treatment. The total walking distance varied from session to session. (N=20)	Usual care included 12 sessions of 45 min conventional gait training, 8 sessions of 45 min conventional physiotherapy (gait training allowed). Total duration of training: 15 hours of treatment for 4 weeks. (N=20)	• 10 metre timed walk (m/sec)

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Visintin1998 [272]	Patients admitted to hospital with stroke (< 6 months ago), not walking with a normal gait pattern and not ambulating before stroke. Follow-up time = 3 months.	Treadmill gait training while an overhead harness supported a percentage of their body weight. Individuals in the body weight support group were provided up to 40% body weight support at the beginning of training, and the percentage of body weight support was progressively decreased as the subject's gait pattern and ability to walk improved. Body weight support treadmill training was given at a frequency of four times per week for 6 weeks (no more than 20 minutes per session). (N=50)	The control group received gait training on a treadmill with no body weight support, i.e. while bearing full weight on their lower extremities. Treadmill without body support was given for 6 weeks at a frequency of four times per week (no more than 20 minutes per session). (N=50)	• 10 metre timed walk (m/sec) • Walking endurance (m)
Hoyer, 2012 [115]	Patients mainly <6 months after onset of stroke, use of wheel-chair, dependence on assistance for walking with or without walking aids, medically stable, no neurological or orthopaedic contraindications for walking.	Treadmill training with body weight support (TTBWS), plus conventional gait training and functional training for a period of minimum 10 weeks. TTBWS was daily for the 1st 4 weeks (20 sessions), and then 1-2 times a week (10 sessions) for the remaining 6 weeks. (N=30)	Intensive gait training (30 min) and functional training (30 min) daily for minimum 10 weeks. (N=30)	• Functional Independence Measure (FIM) • 10 m walk test (m/s) • 6-min walk test (m)
Globas 2012[94]	38 patients with stroke (>6 months) aged >60 years with residual hemiparetic gait (at least 1 clinical sign for paresis, spasticity or circumduction of affected leg while walking); ability to walk on treadmill at ≥0.3km/hr. for 3 minutes with	High-intensity aerobic treadmill exercise (TAEX) for 3 months (39 sessions) starting with 10-20 minutes at 40-50% heart rate reserve (HRR) building up to 30-50 minutes at 60-80% HRR	Conventional Care Physiotherapy (1-3 sessions of 1 hour each/week) including passive muscle tone-regulating exercises for upper and lower extremity, balance training	• Sustained walking ability (6 minute walk). • 10m timed walk at comfortable and maximal speeds;

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
	handrail support.			
Kang 2012[131]	30 Patients with hemiparetic stroke 6 months after diagnosis; who could walk unaided for >15 minutes; without visual disability or hemianopia; Mini-Mental State Examination score 21 or higher; Brunnstrum stage >4.	Treadmill training 3 times a week for 4 weeks, 30 minutes each day – speed increased by 0.1km'hr each time patients could walk stably for 20 seconds; 2 x 15 minutes with 5 minute break	General stretching adding range of motion to both sides of trunk, arms and legs. All patients received conventional physiotherapy 5 times a week for 4 weeks	• 10m walk test, • 6 minute walk test

Comparison: Treadmill training (with or without body support) versus usual care

Table 111: All treadmill training (with or without body support) versus usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	All treadmill training Mean (SD) or median (range)	Usual care Mean (SD) or median (range)	Mean difference (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
6 minute walk test (m) (acute stroke patients) (post treatment effect) (Better indicated by higher values)										
2 Eich 2004[74] Langhammer 2010[143]	RCTs-single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	No serious imprecision	Eich 2004: 198.8 (81.1) Langhammer 2010: 320.6 (153.8)	Eich 2004: 164.4 (69.3) Langhammer 2010: 310.1 (164.4)	31.9 (-8.18, 70.56)	MD 31.19 higher (8.18 lower to 70.56 higher)	Moderate
6 minute walk test (m) (chronic stroke patients) (post treatment effect) (Better indicated by higher values)										
1 Olawale 2011[193] Globas 2012[94] Kang 2012[131]	RCT – unclear blinding	Very serious limitations(b)	No serious inconsistency	No serious indirectness	No serious imprecision	Olawale 145.32 (74.97) Globas 332.1 (138) Kang 242.3 (26)	Olawale 155.27 (66.37) Globas 265.9 (189) Kang 240.9 (22.4)	1.07 (-17.60, 19.75)	MD 1.07 lower (17.60 lower to 19.75 higher)	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	All treadmill training Mean (SD) or median (range)	Usual care Mean (SD) or median (range)	Mean difference (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
6 minute walk test (m) (post treatment)(e) (Better indicated by higher values)										
2 Franceschini 2009[86] Luft 2008[160]	RCTs-single blinded	Very serious limitations (a)	No serious inconsistency	No serious indirectness	(c)	Franceschini 2009: 160 (118-231) Luft 2008: 0.63 (0.52-0.73)	Francesc hini 2009: 170 (90.5-250) Luft 2008: 0.57 (0.46-0.69)	(c)	(c)	Low (c)
6 minute walk test (m) (18 weeks follow-up) (Better indicated by higher values)										
1 Eich 2004[74]	RCTs-single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	No serious imprecision	224.8 (90)	163 (70.2)	61.8 (16.48, 107.12)	MD 61.8 higher (16.48 to 107.12 higher)	Moderate
6 minute walk test (m) (6 months follow-up) (d) (Better indicated by higher values)										
1 Franceschini 2009[86]	RCTs-single blinded	No serious limitations	No serious inconsistency	No serious indirectness	(c)	217 (108.8-332.5)	210 (140-335)	(c)	(c)	High (f)
10 metre timed walk (m/sec) (acute stroke patients) (post treatment effect) (Better indicated by higher values)										
4	RCTs-single	Very serious	No serious	No serious	No serious	Eich 2004:	Eich	0.14 (0.03,	MD 0.14	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	All treadmill training Mean (SD) or median (range)	Usual care Mean (SD) or median (range)	Mean difference (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
Eich 2004[74] Langhammer 2010[143] Laufer 2001[147] Pohl 2002[208]	blinded	limitations (a,h)	inconsistency	indirectness	imprecision	0.7 (0.3) Langhammer 2010: 1.0 (0.4) Laufer 2001: 0.47 (0.4) Pohl 2002: 1.63 (0.8)	2004: 0.6 (0.22) Langhammer 2010: 0.9 (0.5) Laufer 2001: 0.33 (0.24) Pohl 2002: 0.97 (0.64)	0.26)	higher (0.03 lower to 0.26 higher)	
10 metre timed walk (m/sec)(chronic stroke patients) (post treatment effect) (Better indicated by higher values)										
1 Olawale 2011[193] Globas 2012[94] Kang 2012[131]	RCT – unclear blinding	Serious limitations (b)	No serious inconsistency	No serious indirectness	No serious imprecision	Olawale -- 6.71 (0.6) Globas 1.02 (0.38) Kang 0.5 (0.2)	Olawale - 9.28 (0.4) Globas 0.87(0.62) Kang 0.5 (0.1)	0.41 (0.29, 0.53)	MD 0.41 higher (0.29 to 0.53 higher)	Moderate
10 metre timed walk test (m/sec) (post treatment effect)(e) (Better indicated by higher values)										

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	All treadmill training Mean (SD) or median (range)	Usual care Mean (SD) or median (range)	Mean difference (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
2 Franceschini 2009[86] Luft, 2008[160]	RCTs-single blinded	Serious limitations (e)	No serious inconsistency	No serious indirectness	(f)	Franceschini 2009: 0.5 (0.3-0.9) Luft 2008: 0.82 (0.69-0.95)	Franceschini 2009: 0.6 (0.3-0.9) Luft 2008: 0.71 (0.58-0.84)	(g)	(g)	Moderate (f)
10 metre timed walk (m/sec) (mean 29 weeks follow-up) (Better indicated by higher values)										
2 Eich 2004[74] Nilsson 2001[190]	RCTs-single blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	No serious imprecision	Eich 2004: 0.77 (0.35) Nilsson 2001: 0.7 (0.3)	Eich 2004 0.58 (0.22) Nilsson 2001: 0.8 (0.4)	0.07 (-0.06, 0.19)	MD 0.07 higher (0.06 lower to 0.19 higher)	Moderate
10 metre timed walk (m/sec) (6 months follow-up) (c) (Better indicated by higher values)										
1 Franceschini 2009[86]	RCT-single blinded	No serious limitations	No serious inconsistency	No serious indirectness	(f)	0.7 (0.3-1.0)	0.8 (0.5-1.1)	(g)	(g)	High (f)
Walking speed (2-minutes) (m/min) (post treatment effect) (Better indicated by higher values)										
1	RCTs-single	Very serious	No serious	Serious	Serious	11 (9.38)	11 (5.83)	0.00 (-	MD 0.00	Very low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	All treadmill training Mean (SD) or median (range)	Usual care Mean (SD) or median (range)	Mean difference (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
Kosak 2000[138]	blinded	limitations(b)	inconsistency	indirectness (j)	imprecision (i)			4.38, 4.38)	higher (4.38 lower to 4.38 higher)	
Walking endurance (m) (post treatment effect) (Better indicated by higher values)										
1 Kosak 2000[138]	RCT-single blinded	Very serious limitations(b)	No serious inconsistency	Serious indirectness (j)	Serious imprecision(i)	74 (70.36)	72 (64.14)	2.00 (-34.46, 38.46)	MD 2.00 higher (34.46 lower to 38.46 higher)	Very low
Walking endurance (m) (6 weeks follow-up) (Better indicated by higher values)										
1 Kuys 2011[139]	RCT-single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Very serious imprecision(k)	284 (139)	279 (163)	5.00 (-106.86,116.86)	MD 5 higher (106.86 lower to 116.86 higher)	Low
Walking endurance (m) (18 weeks follow-up) (Better indicated by higher values)										
1 Kuys 2011[139]	RCT-single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Very serious imprecision(k)	291 (157)	293 (180)	-2.00 (-137.14, 133.14)	MD 2 lower (137.14 lower to 133.14	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	All treadmill training Mean (SD) or median (range)	Usual care Mean (SD) or median (range)	Mean difference (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
									higher)	
Comfortable walking speed (m/sec) (6 weeks follow-up) (Better indicated by higher values)										
1 Kuys 2011[139]	RCT-single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Very serious imprecision(k)	0.63 (0.3)	0.68 (0.37)	-0.05 (-0.3, 0.2	MD 0.05 lower (0.3 lower to 0.2 higher)	Low
Comfortable walking speed (m/sec) (18 weeks follow-up) (Better indicated by higher values)										
1 Kuys 2011[139]	RCT-single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Very serious imprecision(k)	0.72 (0.35)	0.66 (0.41)	0.06 (-0.25, 0.37)	MD 0.06 higher (0.25 lower to 0.37 higher)	Low
Fast walking speed (m/sec) (6 weeks follow-up) (Better indicated by higher values)										
1 Kuys 2011[139]	RCT-single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Very serious imprecision(k)	0.86 (0.43)	0.86 (0.47)	0 (-0.33, 0.33)	MD 0 higher (0.33 lower to 0.33 higher)	Low
Fast walking speed (m/sec) (18 weeks follow-up) (Better indicated by higher values)										
1	RCT-single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Very serious imprecision(	0.91 (0.46)	0.82 (0.49)	0.09 (-0.29, 0.47)	MD 0.09 higher	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	All treadmill training Mean (SD) or median (range)	Usual care Mean (SD) or median (range)	Mean difference (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
Kuys 2011[139]					k)				(0.29 lower to 0.47 higher)	
FIM motor items (10 months follow-up) (Better indicated by higher values)										
1 Nilsson 2001[190]	RCT-single blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(l)	81.9 (9.6)	80.3 (15.9)	1.6(-4.96, 8.16)	MD 1.6 higher (4.96 lower to 8.16 higher)	Low
FIM cognitive items (10 months follow-up) (Better indicated by higher values)										
1 Nilsson 2001[190]	RCT-single blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(m)	32 (5)	31.5 (6.6)	0.50 (-2.44, 3.44)	MD 0.50 higher (2.44 lower to 3.44 higher)	Low
Barthel Index (post treatment effect) (Better indicated by higher values)										
1 Franceschini 2009[86]	RCTs-single blinded	No serious limitations	No serious inconsistency	No serious indirectness	(f)	3 (2-4)	2 (1-3.5)	(g)	(g)	High (f)
Barthel Index (6 months follow-up) (Better indicated by higher values)										
1	RCTs-single	No serious	No serious	No serious	(f)	4 (4-5)	4 (3-5)	(g)	(g)	High (f)

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	All treadmill training Mean (SD) or median (range)	Usual care Mean (SD) or median (range)	Mean difference (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
Franceschini 2009[86]	blinded	limitation	inconsistency	indirectness						
Rivermead gross function (post treatment effect) (Better indicated by higher values)										
1 Eich 2004[74]	RCT-single blinded	Very serious limitations(a)	No serious inconsistency	No serious indirectness	(f)	11 (11)	11 (10-11)	(g)	(g)	Low (f)
Rivermead Motor Assessment Score (18 weeks follow-up) (Better indicated by higher values)										
1 Eich 2004[74]	RCT-single blinded	Very serious limitations(a)	No serious inconsistency	No serious indirectness	(f)	11 (11)	11 (10-11)	(g)	(g)	Low (f)

(a) Inadequate randomisation (Eich 2004; Langhammer 2010; Laufer 2001; Nilsson 2001; Kang 2012)
(b) Unclear blinding (Globas 2012), randomisation method and allocation concealment (Olawale 2011; Kossak 2000)
(c) This outcome is presented separately for the studies that could not be meta-analysed as the results were not presented with the mean and standard deviation
(d) High drop-out rate - 35% in experimental group and 39% in control group (Luft 2008)
(e) Imprecision could not be assessed because only median and interquartile ranges of data were reported.
(f) Relative and absolute effect could not be assessed because median and interquartile ranges of data reported
(g) Unclear allocation concealment (Laufer 2001; Pohl 2002)
(h) Confidence interval crossed one end of default MID.
(i) Control group received aggressive bracing assisted walking exercise.
(j) Confidence interval crossed both ends of default MID.
(k) Confidence interval crossed one end of agreed MID (17 points).
(l) Confidence interval crossed one end of agreed MID (3 points).

Comparison: Early treadmill training exercise (2 months after stroke) with body weight support versus home exercise program

Table 112: Early treadmill training exercise (2 months after stroke) with body weight support versus home exercise program – Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
						Early body weight support treadmill	Home exercise program	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Mean (SD)	Mean (SD)	Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
10 metre timed walk test (m/sec) (post treatment effect) (Better indicated by higher values)										
1 Duncan 2011[73]	RCT-Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (a)	0.25(0.21)	0.23(0.20)	0.02 (-0.03, 0.07)	MD 0.02 higher (0.03 lower to 0.07 higher)	Moderate
10 metre timed walk test (m/sec) (6 months follow-up) (Better indicated by higher values)										
1 Duncan 2011[73]	RCT-Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (a)	0.23 (0.20)	0.25(0.22)	-0.02 (-0.07, 0.03)	MD 0.02 lower (0.07 lower to 0.03 higher)	Moderate
6 minute walk test (m) (post treatment effect) (Better indicated by higher values)										
1 Duncan 2011[73]	RCT-Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Serious imprecision (b)	81.8 (62.8)	75.9 (69.3)	5.9 (-10.08, 21.88)	MD 5.9 higher (10.08 lower to 21.88 higher)	Moderate

Quality assessment						Summary of findings				
						Early body weight support treadmill	Home exercise program	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Mean (SD)	Mean (SD)	Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
6 minute walk test (m) (6 months follow-up) (Better indicated by higher values)										
1 Duncan 2011[73]	RCT-Single blinded	No serious limitations	No serious inconsistency	No serious indirectness	Very serious imprecision (b)	73.2 (69.4)	85.2 (72.9)	-12.0 (-29.18, 5.18)	MD 12.0 lower (29.18 lower to 5.18 higher)	Moderate

(a) Confidence interval both ends of default MID.
(b) Mean difference did not reach the agreed MID of 28 m.

Comparison: Treadmill training exercise with body support versus treadmill training exercise without body support

Table 113: Treadmill plus body weight support versus treadmill only - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
						Body weight support treadmill	Treadmill only	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Mean (SD), Frequency (%)	Mean (SD), Frequency (%)	Mean difference /Risk Ratio (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
10 metre timed walk (m/sec) (post treatment effect) (Better indicated by higher values)										
2 Hoyer 2012 [115], Visintin 1998[272]	RCT-Single blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	No serious imprecision	Hoyer: 0.33 (0.24) Visintin: 0.34 (0.26)	Hoyer: 0.32 (0.22) Visintin: 0.25 (0.36)	0.04 (-0.05, 0.13)	MD 0.04 higher (0.05 lower to 0.13 higher)	Moderate
10 metre timed walk (m/sec) (11 – 12 weeks follow-up) (Better indicated by higher values)										
2 Hoyer 2012 [115], Visintin 1998[272]	RCT-Single blinded	Very serious limitations (a, b)	Serious inconsistency(i)	No serious indirectness	No serious imprecision	Hoyer: 0.4 (0.27) Visintin: 0.52 (0.32)	Hoyer: 0.36 (0.24) Visintin: 0.30 (0.29)	0.11 (0.01, 0.21)	MD 0.11 higher (0.01 to 0.21 higher)	Very low
Walking endurance (m) (post treatment effect) (Better indicated by higher values)										
1 Visintin 1998[272]	RCT-Single blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Very serious imprecision(c)	147.4 (119.35)	105 (112.2)	42.4 (-8.75, 93.55)	MD 42.4 higher (8.75 lower to 93.55 higher)	Very low

Quality assessment						Summary of findings				
						Body weight support treadmill	Treadmill only	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Mean (SD), Frequency (%)	Mean (SD), Frequency (%)	Mean difference /Risk Ratio (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
Walking endurance (m) (3 months follow-up) (Better indicated by higher values)										
1 Visintin 1998[272]	RCT-Single blinded	Very serious limitations (a,b)	No serious inconsistency	No serious indirectness	Very serious imprecision (c)	202.4 (122.78)	152.3 (141)	50.10 (-22.82, 123.02)	MD 50.1 higher (22.82 lower to 123.02 higher)	Very low
Proportion of participants achieved over ground walking speed over 0.2 m/s (post-treatment effect)										
1 Barbeau[15]	RCT- Double blinded	Serious limitations(d)	No serious inconsistency	No serious indirectness	Very serious imprecision (e)	17/50	13/50 (26%)	RR 1.31 (0.71 to 2.4)	81 more per 1000 (from 75 fewer to 364 more)	Very low
Proportion of participants achieved over ground walking endurance over 20 m (post-treatment effect)										
1 Barbeau[15]	RCT- Double blinded	Serious limitations(d)	No serious inconsistency	No serious indirectness	Serious imprecision (f)	24/50 (48%)	19/50 (38%)	RR 1.26 (0.8 to 1.99)	99 more per 1000 (from 76 fewer to 376 more)	Low
6 metre walk test (m) (post treatment effect) (better indicated by higher values)										
1 Hoyer 2012 [115]	RCT- single blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(g)	108.39 (76.84)	98.03 (61.90)	10.36 (-24.95, 45.67)	MD 10.36 higher (24.95 lower to	Low

Quality assessment						Summary of findings				
						Body weight support treadmill	Treadmill only	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Mean (SD), Frequency (%)	Mean (SD), Frequency (%)	Mean difference /Risk Ratio (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
									45.67 higher)	
6 metre walk test (m) (11 weeks follow up) (Better indicated by higher values)										
1 Hoyer 2012 [115]	RCT- single blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision(g)	108.39 (76.84)	98.03 (61.90)	22.23 (-22.91, 67.37)	MD 22.23 higher (22.91 lower to 67.37 higher)	Low
Functional Independence Measure 9, shorter transfer (sec): (Post intervention) (Better indicated by lower values)										
1 Hoyer 2012 [115]	RCT- single blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Very serious imprecision(h)	40.32 (28.98)	45.67 (28.61)	-5.35 (-19.92, 9.22)	MD 5.35 lower (19.92 lower to 9.22 higher)	Very low
Functional Independence Measure 9, shorter transfer (sec): (11 weeks follow up) (Better indicated by lower values)										
1 Hoyer 2012 [115]	RCT- single blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Very serious imprecision(h)	33.02 (25.07)	39.85 (31.89)	-6.83 (-21.35, 7.69)	MD 6.83 lower (21.35 lower to 7.69 higher)	Very low
Functional Independence Measure 13, Stairs Nine steps up - down transfer (sec): (Post intervention) (Better indicated by lower values)										

Quality assessment						Summary of findings				
						Body weight support treadmill	Treadmill only	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Mean (SD), Frequency (%)	Mean (SD), Frequency (%)	Mean difference /Risk Ratio (95% CI)	Absolute effect / Mean Difference (MD) (95% CI)	Confidence (in effect)
1 Hoyer 2012 [115]	RCT- single blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Very serious imprecision(h)	61.31 (43.04)	80.79 (61.55)	-19.48 (-46.36, 7.40)	MD 19.48 lower (46.36 lower to 7.40 higher)	Very low
Functional Independence Measure 13, Stairs Nine steps up - down transfer (sec): (11 weeks follow up) (Better indicated by lower values)										
1 Hoyer 2012 [115]	RCT- single blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	Very serious imprecision(h)	48.4 (31.82)	67.03 (51.70)	-18.63 [-40.35, 3.09]	MD 18.63 lower (40.35 lower to 3.09 higher)	Very low

(a) Unclear allocation concealment.
(b) High drop-out rate (34%) during follow-up for Vinsintin
(c) Confidence interval crossed both ends of default MID.
(d) Unclear allocation concealment. 28% of the control group did not complete the study.
(e) Confidence interval crossed both ends of default MID (0.75, 1.25).
(f) Confidence interval crossed the upper limit of MID (1.25).
(g) Confidence interval crosses one end of agreed MID (28m)
(h) Confidence interval crosses both ends of default MID (0.5)
(i) Heterogeneity: I = 64%

13.8.2.2 Economic evidence

Literature review

No relevant economic evaluations were identified comparing treadmill training with usual care, or treadmill training with body support with treadmill training without body support.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

In most studies identified in the clinical review the main difference in terms of resources use between treadmill training and usual care was the use of the treadmill and there was no substantial difference in personnel time. Illustrative treadmill costs are presented below.

A GDG member supplied price data on a specific type of treadmill without body support unit. This data was obtained from the manufacturer of the treadmill (Cranlea & Co Medical). The treadmill model was a Woodway model desmohip, and its cost amounted to £9,421 (2011 prices), with an additional £500 estimated as delivery and installation costs. The GDG also supplied data regarding the rate of utilisation of a treadmill without body weight support for an NHS Trust with an inpatient sub-acute stroke rehabilitation service (based at Guy's and St Thomas' NHS Foundation Trust) where patients are usually 0-60 days post stroke. The treadmill alone is used to the level of approximately 2-4 treatment sessions each day, where each session lasts for about 1 hour. Annuitising this cost assuming a useful lifetime of 5 years, no resale value and a discount rate of 3.5%, and assuming usage of 3 sessions per day, this would equate to a cost per session of £1.94.

The estimate for the cost of a treadmill with body weight support was obtained by contacting the author of a US study (Walker, 2010[279])**.**The overall cost quoted by the author was of $20,000 (of which $2,000 was the cost of the treadmill alone), equivalent to £13,029 (at 2009 prices). The manufacturer of the treadmill and of the BSW unit was Biodex (a US company). A GDG member supplied data regarding the rate of utilisation of a treadmill with body weight support for an NHS Trust with an inpatient sub-acute stroke rehabilitation service (based at Guy's and St Thomas' NHS Foundation Trust) where patients are usually 0-60 days post stroke. The treadmill with BWS unit is used for approximately 1 patient per month for approximately 4-6 treatments overall. Annuitising this cost assuming a useful lifetime of 5 years, no resale value and a discount rate of 3.5%, and assuming usage of 5 sessions per month, this would equate to a cost per session of £46.47.

13.8.2.3 Evidence statements

Clinical evidence statements

Two studies[74, 143] of 83 participants with acute stroke found that there was no significant difference in walking capacity (6 minute walk test) (m) between the participants who received treadmill training with no body weight support and those who had usual care at the end of the study (MODERATE CONFIDENCE IN EFFECT).

Three studies [193] [94,131] of 100 participants with chronic stroke (up to 24 months post-stroke) found that there was no significant difference in walking capacity (6 minute walk test) (m) between those who received treadmill training without body weight support and the usual care group at the end of the study (LOW CONFIDENCE IN EFFECT).

One study[74] of 49 participants found that treadmill training with no body weight support was associated with a statistically significant improvement in walking capacity (6 minute walk test) (m) compared to those receiving usual care at the end of the 18 weeks follow-up (MODERATE CONFIDENCE IN EFFECT).

Four studies[74,143,147,208] comprising of 148 participants with acute stroke found a statistically significant improvement in gait speed (10 metre timed walk test)(m/sec) in those who received treadmill training with no body weight support compared to those who received usual care at the end of the study (LOW CONFIDENCE IN EFFECT).

Three studies [193] [94,131] of 100 participants with chronic stroke (up to 24 months post-stroke) found a statistically significant larger improvement in gait speed (10 metre timed walk test) (m/sec) in those who received treadmill training, compared to those who received usual care at the end of the study (MODERATE CONFIDENCE IN EFFECT).

Two studies[74,190] comprising of 102 participants found no significant difference in gait speed (10 metre timed walk test) (m/sec) between the all treadmill training group (with and without body weight support) and those who received usual care at the end of the follow-up (average 29 weeks) (MODERATE CONFIDENCE IN EFFECT).

One study[138] comprising of 56 participants found no significant difference between the partial body weight support treadmill group and those who received aggressive bracing assisted walking at the end of the study on the following outcomes:

- walking speed over a 2-minute test period (m/minute)(VERY LOW CONFIDENCE IN EFFECT)
- walking endurance (m) (VERY LOW CONFIDENCE IN EFFECT).

One study[190] comprising of 60 participants found no significant difference between the treadmill training group with body weight support and those who received usual care at 10 months follow-up on the following outcomes:

- FIM motor items (LOW CONFIDENCE IN EFFECT)
- FIM cognitive items (LOW CONFIDENCE IN EFFECT).

One study[139] comprising of 30 participants found no significant difference between the participants received the treadmill training group and those who received usual care at 6 and 18 months follow-up on the following outcomes:

- walking endurance (LOW CONFIDENCE IN EFFECT)
- comfortable walking speed (m/sec) (LOW CONFIDENCE IN EFFECT)
- fast walking speed (m/sec) (LOW CONFIDENCE IN EFFECT).

One study[73] comprising of 265 participants found that there was significant difference between the participants who received early body weight supported treadmill training and those who received home exercise program on the following outcomes:

- 10 metre timed walk test (m/sec) at the end of the study and 6 months follow-up (MODERATE CONFIDENCE IN EFFECT)
- 6 minute walk test (m) at the end of the study and 6 months follow-up (MODERATE CONFIDENCE IN EFFECT)

Two studies[272], [115] comprising of 139 participants found no significant difference (in 10 metre timed walk test) between the participants who received body weight supported treadmill training and those who received only treadmill training post intervention (MODERATE CONFIDENCE IN EFFECT)

Two studies[272], [115] comprising of 139 participants showed significant difference in 10 metre timed walk test in favour of the participants who received body weight supported treadmill training

compared with those who received only treadmill training at the end of follow-up (VERY LOW CONFIDENCE IN EFFECT)

One study[272] comprising of 100 participants found no significant difference between the participants who received body weight supported treadmill training and those who had only treadmill training on the following outcomes:

- walking endurance (m) at the end of the study (VERY LOW CONFIDENCE IN EFFECT)
- walking endurance (m) at 3 months follow-up (VERY LOW CONFIDENCE IN EFFECT).

One study[15]comprising of 100 participants found that there was no significant difference on the proportion of participants achieved over ground walking speed over 0.2 m/s between those who received body weight supported treadmill and those who had only treadmill training (VERY LOW CONFIDENCE IN EFFECT).

One study[15]comprising of 100 participants found that there was no significant difference on the proportion of participants achieved over ground walking endurance over 20 m between those who received body weight supported treadmill and those who had only treadmill training (LOW CONFIDENCE IN EFFECT).

One study [115] comprising 60 participants found no significant difference (in 6 metre walk test) between the group that received body weight treadmill and the group that received only treadmill post intervention and at the end of follow-up (LOW CONFIDENCE IN EFFECT)

One study [115] comprising 60 participants found no significant difference (in the Functional Independence measure scales 9 and 13) between the group that received body weight treadmill and the group that received only treadmill post intervention and at the end of follow-up (VERY LOW CONFIDENCE IN EFFECT)

Evidence statements could not be produced for the following outcome(s) as results were not presented in a way that enabled the size of the intervention's effect to be estimated:

- Barthel index (treadmill with or without body weight support versus usual care)[86]
- Rivermead gross function (treadmill with or without body weight support versus usual care)[74]

Economic evidence statements

No cost-effectiveness evidence was identified.

13.8.3 Recommendations and link to evidence

	100. Offer walking training to people after stroke who are able to walk, with or without assistance, to help them build endurance and move more quickly. **101. Consider treadmill training, with or without body weight support, as one option of walking training for people after stroke who are able to walk with or without assistance.**

Relative values of different outcomes	The outcomes considered in the evidence review were: walking speeds (5 m/ 10 m / 30 m), timed walk, walking endurance, FIM, Barthel and Rivermead Mobility Index. The GDG considered outcomes demonstrating changes in walking to be of more significance. Overall, the sixteen (16) studies included in the review showed there was an improvement in walking outcomes in both the intervention and control groups, but treadmill provided no greater improvement than other forms of physiotherapy.
Trade-off between clinical benefits and harms	The patient representatives on the group felt that too much emphasis was being placed on distance and speed, and that for patients, the primary concern was the motivation to walk from point A to B safely and feeling comfortable. They felt that speed of walking would not be a significant concern of patients. Group members noted that the trials were conducted in a gym setting and this would not necessarily translate to walking outdoors. The consensus view was that variety was an important part of rehabilitation treatment for patients, and treadmill is a reasonable tool for use in gait training for people who are already walking and can increase walking speed and capacity.
Economic considerations	No relevant cost effectiveness studies were identified. The main difference in cost of using treadmill training over usual care was considered to be the cost of the treadmill. The capital cost of a treadmill is high at around £10,000, however when this cost is spread over the lifetime of the equipment and the amount of usage it gets the cost per patient per session was estimated at £2 for treadmill without body weight support, and £47 for treadmill with body weight support. The GDG also noted that a treadmill may already be available in many hospitals and used for purposes other than stroke rehabilitation; if currently not fully utilised, use in stroke patients could be accommodated without incurring the full costs estimated.
Quality of evidence	All the studies were small (range of participants in the included studies 25-113). The studies using both the 6 minute walk test and 10 metre timed walk as measurements over different follow-up periods present mixed results but overall showed no significant difference between the intervention arm (treadmill with or without body weight) and the control arm in walking capacity or gait speed outcomes. Confidence in the results for walking capacity and speed outcomes was moderate to very low due to limitations in study design or imprecision in the effect estimate. The GDG noted that all the people within the studies had some walking capacity except for one trial [86]. The GDG questioned why the results in the Visintin study (1998) showed there was late gain achieved in the 10 metre walk outcome when there was no immediate response after the intervention. After discussion, the GDG concluded that it may be that with body support better gait is achieved and therefore this would explain the late gain. There were also differences in gait speed between the two groups which may have allowed the intervention arm to reach a certain threshold. The GDG concluded that the patients within the trials used in the clinical evidence could already walk with some support; therefore the recommendation should state that this group are most likely to benefit from treadmill.
Other considerations	Treadmill facilities are widely available in rehabilitation units and the

	GDG agreed that treadmill was one method of delivering an intensive treatment. As treadmill was found to be as good as conventional therapy the GDG agreed it could be considered for patients. Patients currently would usually receive fixed amounts of therapy which includes treadmill training as part of their rehabilitation therapy. If patients are stable then treadmill users can work with minimal supervision once they are set up on the equipment. Treadmill enables patients to get much more practice walking than they can by walking outdoors and it also offers the opportunity to do forced speed training. The GDG agreed that treadmill was a useful tool and offered some benefit to the patients after stroke even if no greater than usual care. The GDG agreed that it was important for everyone to be offered walking training, and this was backed up by the evidence reviewed which showed both arms of studies making an improvement following walking exercises.

13.9 Electromechanical gait training

An electromechanical gait trainer is a robotic gait assistive device that is designed to provide physical support and mechanical walking action during gait re-education. There are several types of electromechanical gait training interventions that provide repetitive locomotor therapy. Locomat and Reha-stim are the trade-names of the trainers used in the studies considered. Both are robotic, or servo controlled motor assisted devices, and provide variable amounts of assistance during walking training, including timing of leg movements with the option of body weight support (up to 40%). The advocates of electromechanical gait trainers claim that it improves walking by stimulating a normal, symmetrical gait cycle.

Asymmetrical muscle weakness, tonal changes, loss of sensation including proprioception, and poor balance and coordination are major obstacles in the successful rehabilitation of gait in the recovering stroke patient. The use of assistive devices such as electromechanical gait trainer aims to assist in the re- education of gait through supported repetition of walking behaviour.

The use of the aid is assumed to be in the context of a professionally directed rehabilitation programme to improve walking ability. A suitably qualified Physiotherapist and assistant will be required to design the appropriate walking training, position the patient correctly and to encourage and advise throughout the duration of the intervention.

This type of intervention may be used throughout any stage in the rehabilitation following stroke as long as the patient is medically fit and has no contraindications to exercise.

Due to the cost and scarcity of the equipment this form of intervention is rarely seen within NHS facilities.

13.9.1 Evidence review: In people after stroke what is the clinical and cost effectiveness of electromechanical gait training versus usual care on improving function and reducing disability?

Clinical Methodological Introduction	
Population	Adults and young people 16 or older who have had a stroke
Intervention	Electromechanical gait training Locomat training
Comparison	Usual care
Outcomes	• Walking speeds (5 metres/ 10 metres / 30 metres) • Any timed walk • Walking endurance

Clinical Methodological Introduction	
	• Functional Independence Measure (FIM) • Barthel Index • Rivermead Mobility Index

13.9.1.1 Clinical evidence review

Searches were conducted for systematic reviews and RCTs comparing the effectiveness of electromechanical gait training with usual care as interventions for improving function and reducing disability for adults and young people 16 or older who have had a stroke. Only studies with a minimum sample size of 20 participants (10 in each arm) and including at least 50% of participants with stroke were selected. Eleven RCTs were identified. **Table 114** summarises the population, intervention, comparison and outcomes for each of the studies.

Table 114: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix H.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Dias, 2007[64]	Single incident chronic stroke patients (>12 months ago) with lower limb motor deficit.	Gait trainer/ Reha-Stim (40 minutes per session, 5 times/week for 5 weeks): patients were harness secured and positioned on two footplates supervised by a physiotherapist; a servo-controlled motor assisted the gait movement by controlling the gear velocity with a max of 30% body weight relief during the first sessions. (N=20)	Usual care: patients followed the classic Bobath method and rehabilitation management, including an initial 20 minutes session for joint mobilisation and muscle strengthening plus 20 minutes balance and gait training. (N=20)	• Rivermead Mobility Index • Barthel Index • 10 metre timed walk test (m/sec) • 6 minute walk test (m)
Hidler, 2009[110]	First time stroke; time since stroke onset <6 months; ability to ambulate 5 meters without physical assistance and a self-selected walking speed between 0.1 to 0.6 m/s	Lokomat gait or robotic-assisted training (3 days/weeks for 8-10weeks to a maximum total of 24 sessions (1.5 hours each session)): patients were harness-secured with up to 40% body weight support with the level of body support decreased incrementally per session. The training intensity was increased by changing the speed and the level of body-weight support and duration of continuous walking (N=36).	Conventional gait training: focused on therapist-assisted static and dynamic postural tasks, trunk positioning, improving lower and upper limb range of motion, over ground walking, then higher level balance and gait activities including stairs. (N=36)	• 5 metre timed walk test (self-selected velocity) (m/sec) • 6 minute walk test (m) • Rivermead Mobility Index
Hornby, 2008[114]	Patients with hemiparesis of >6months duration after stroke; ability to	Robotic-assisted locomotor training (Lokomat) (a total of 12 sessions for 30 minutes/session): patients	Therapist assisted locomotor training (a total of 12 sessions for 30	• 6 minute walk test (m) • 10 metre timed walk

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
	walk >10m without physical assistance at speeds of at least 0.8m/s at self-selected velocity using assistive devices and bracing below the knee as needed.	were harness-secured to provide 30-40% body weight in the first session and decreased approximately 10% increments per session as tolerated without substantial knee buckling or toe drag. (N=31)	minutes/session): patients were harness-secured and trained at similar weight support and speeds to robotic assisted group. (N=31)	test (self-selected velocity) (m/sec)
Husemann, 2007[118]	First time stroke patients with severe hemiparesis with lower extremity strength graded 3 or less on MRC scale in >2 muscle groups. Interval between stroke and start of treatment 28 - 200 days.	Robotic-assisted training (a total of 40 sessions (30 minutes/ session) for 4 weeks): patients walked on a treadmill with the help of a Lokomat. 30% of body weight of each subject was supported initially. The velocity of the treadmill set to the maximum speed tolerated by the patients, force of the drives regulated and body weight support was reduced as soon as patients could tolerate it. Patients also received 30 minutes physiotherapy sessions. (N=17)	Therapist-assisted gait rehabilitation: exercising trunk stability and symmetry, step initiation and weight support. Treadmill training was provided if possible with the help of therapists. Patients also received 30 minutes physiotherapy sessions. (N=15)	• 10 metre timed walk test (m/sec) • Barthel Index (German version)
Peurala 2005[204]	Chronic first time stroke patients (>6 months) who had slow or difficult walking	Gait trainer/Reha-Stim (20 minutes/ session for a total of 3 weeks): supported with a harness and their feet were on motor-driven footplates + partial body weight support verbally or manually guided by physiotherapists (N=15)	Walking overground: practised overground or over uneven terrain with walking aids. (N=15)	• 10 metre timed walk (m/sec) • 6 minute walk test (m) • Functional Independence Measure (FIM) (total score)
Peurala 2009[203]	First time stroke patients (within 10 days of stroke onset)	Gait trainer/Reha-Stim) (in total of 15 sessions for 3 weeks): patients were supported with a harness and their feet were supported on motor-driven footplates. Amount of body support was chosen according to individual needs. (N=22)	Control group 1 Walking training: patients practised walking overground with 1 or 2 physiotherapists, using walking aids. (N=21) Control group 2 Conventional treatment: patients received one or 2 physiotherapy sessions daily, but	• 10 metre timed walk (m/sec) • 6 minute walk test (m) • Rivermead Mobility Index

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
			not at the same intensity as the other two groups. (N=13)	
Pohl, 2007[209]	First time stroke patients (<60 days); able to sit unsupported with feet supported, could not walk at all, or required the help of one or two therapists irrespective of the use of an ankle-foot orthosis or a walking aid.	Gait trainer/Reha-Stim (every week day for 4 weeks): patients received 20 minutes of repetitive locomotor therapy on the gait trainer, immediately followed by 25 minutes of one-to-one physiotherapy every week day for 4 weeks (N=77)	Usual care: patients received 45-minute physiotherapy. (N=78)	• Barthel Index • 10 metre timed walk (m/sec) • 6 minute walk test (m) • Rivermead Mobility Index
Schwartz, 2009[233]	First time stroke patients (<3 months) who were independent ambulated before the stroke.	Robotic-assisted gait training (Lokomat) (30 minutes/session/work-day, 3 times a week for 6 weeks): the speed of treadmill set to maximum tolerated by the patients. Approximately 50% of body weight supported by harness initially, the support was gradually reduced in approximately 10% increments per session as tolerated without substantial knee buckling or toe drag. Patients also received regular physiotherapy. (N=37)	Usual care: patients treated with additional regular physiotherapy for gait training for 30 minutes (overall 60 minutes of regular physiotherapy) 3 times a week. In every session the patient walked some steps with the help of therapists. (N=30)	• FIM • 10 metre timed walk test (m/sec)
Tong, 2006[260]	First stroke patients admitted to inpatient rehabilitation unit in Hong Kong (<6 weeks after onset of stroke) with significant gait deficit (FAC score <3); ability to stand upright, supported or unsupported for 1 min.	Electromechanical gait trainer/Reha-Stim (1 training session of 20min/week day over a total of 4 weeks): gait trainer stimulated a normal gait cycle in a symmetric manner with a ratio of 60-40% between the stance and swing phases. Body weight partially supported by a harness. Patients had also regular weekday 40min physiotherapy sessions and 1.5hour multi-disciplinary treatments. (N=15)	Control gait training: training based on principles of proprioceptive neuromuscular facilitation and Bobath concepts by a physical therapist. Patients had also regular weekday 40min physiotherapy sessions and 1.5hour multi-disciplinary treatments. (N=20)	• 5 metre timed walk (m/sec) • FIM • Barthel index

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Werner 2002[281]	Sub acute, non-ambulatory hemiparetic patients (4-12 weeks after stroke)	Gait trainer/Reha-Stim (15-20 minutes/ session for 2 weeks): harness-secured patients were positioned on 2 footplates. A servo-controlled motor assisted the gait movement; body weight was partially supported and the support was gradually reduced. (N=15)	Treadmill training: motor-driven treadmill, patients wore a modified parachute harness and a pulley released part of the body weight. (N=15)	• 10 metre timed walk (m/sec) (maximum speed)
Morone 2012[179]	Participants with sub-acute stroke stratified into groups according to motor impairments (low motricity and high motricity groups). The authors used the motricity index score with a cut-off of ≤29 to define a low motricity (LM) group of patients versus a group of patients with high motricity (HM; MI > 29).	Gait trainer/Reha-Stim: 2 therapy sessions per day 5 days per week for 3 months; Gait Trainer for first 4 weeks (N=24)	Conventional gait training (N=24)	• Functional ambulation Classification • Barthel Index • Rivermead Mobility Index

Comparison: Electromechanical gait training versus usual care

Table 115: Electromechanical gait training versus usual care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Electro-mechanical gait training Mean (SD)/ median (IQR)	Usual care Mean (SD) /median (IQR)	Mean difference (95% CI)	Standardised Mean Difference (SMD) / Mean Difference (MD) (95% CI)	Confidence (in effect)
5 and 10 metre timed walk (m/sec) (post treatment effect) (Better indicated by higher values)										
6 Hornby 2008[114] Husemann 2007[118] Peurala 2005[204] Pohl 2007[209] Tong 2006[260] Werner 2002[281]	RCTs- 2 single blinded, 3 unblinded, 1 cross over trial	Very serious limitations (a)	No serious inconsistency	No serious indirectness	No serious imprecision	Change from baseline Hornby: 0.52 (0.21) Husemann: 0.2 (0.12) Pohl: 0.44 (0.47) Tong: 0.47 (0.21) Werner: 0.42 (0.21) Final values Peurala: 35.9 (29.9)	Change from baseline Hornby: 0.56 (0.28) Husemann :0.2 (0.18) Pohl: 0.32 (0.36) Tong: 0.24 (0.30) Werner: 0.37 (0.23) Final values Peurala:	0.22 (-0.00, 0.43)	SMD 0.22 higher (0.00 lower to 0.43 higher)	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Electro-mechanical gait training Mean (SD)/ median (IQR)	Usual care Mean (SD) /median (IQR)	Mean difference (95% CI)	Standardised Mean Difference (SMD) / Mean Difference (MD) (95% CI)	Confidence (in effect)
							32.1 (15.9)			
5 metre timed walk (m/sec) (post treatment effect)*(Better indicated by higher values)										
1 Hidler 2009[110]	RCT – unblinded	Very serious limitations (b)	No serious inconsistency	No serious indirectness	No serious imprecision	0.12 (0.03)	0.25 (0.03)	-0.13 (-0.14,-0.12)	MD 0.13 lower (0.14 to 0.12 lower)	Low
5 metre timed walk (m/sec) (3 months follow-up) (Better indicated by higher values)										
1 Hidler 2009[110]	RCT – unblinded	Very serious limitations (b)	No serious inconsistency	No serious indirectness	No serious imprecision	0.15 (0.04)	0.30 (0.03)	-0.15 (-0.17, -0.13)	MD 0.15 lower (0.17 to 0.13 lower)	Low
10 metre timed walk (m/sec) (6 months follow-up) (>6 months stroke onset) ^(Better indicated by higher values)										
1 Hornby 2008[114]	RCTs – single blinded	Very serious limitations (c)	No serious inconsistency	No serious indirectness	Serious imprecision (d)	0.50 (0.21)	0.52 (0.25)	-0.02 (-0.13, 0.09)	MD 0.02 lower (0.13 lower to 0.09 higher)	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Electro-mechanical gait training Mean (SD)/ median (IQR)	Usual care Mean (SD) /median (IQR)	Mean difference (95% CI)	Standardised Mean Difference (SMD) / Mean Difference (MD) (95% CI)	Confidence (in effect)
10 metre timed walk (m/sec) (6 month follow-up) (<2 months stroke onset) ^(Better indicated by higher values)										
1 Pohl 2007[209]	RCTs - unclear blinding	Serious limitations (e)	No serious inconsistency	No serious indirectness	Serious imprecision (d)	0.53 (0.31)	0.36 (0.42)	0.17 (-0.05, 0.29)	MD 0.17 higher (0.05 lower to 0.29 higher)	Low
6 minute walk test (m) (post treatment effect) (Better indicated by higher values)										
4 Hornby 2008[114] Peurala 2005[204] Pohl 2007[209] Dias 2007[64]	RCTs- 2 single blinded, 1 unblinded, 1 trial with unclear blinding	Very serious limitations (f)	No serious inconsistency	No serious indirectness	Serious imprecision (q)	Change from baseline Dias: -18.92 (26.33) Final values Hornby: 186 (88) Pohl: 134.4 (125.5) Peurala: 151.7	Change from baseline Dias: -23.28 (2.16) Final values Hornby: 204 (96) Pohl: 92.5 (104.9) Peurala:	0.20 (-0.03, 0.44)	SMD 0.20 higher (0.03 lower to 0.44 higher)	Very low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Electro-mechanical gait training Mean (SD)/ median (IQR)	Usual care Mean (SD) /median (IQR)	Mean difference (95% CI)	Standardised Mean Difference (SMD) / Mean Difference (MD) (95% CI)	Confidence (in effect)
						(97.4)	135.1 (67.9)			
6 minute walk test (m) (post treatment effect) (change in scores from the baseline*) (Better indicated by higher values)										
1 Hidler 2009[110]	RCT - unblinded	Very serious limitations (b)	No serious inconsistency	No serious indirectness	No serious imprecision	50.17 (9.906)	83.515 (10.79)	-33.34 (-38.13, -28.56)	MD 33.34 lower (38.13 to 28.56 lower)	Low
6 minute walk test (m) (self-selected) (3 months follow-up) (Better indicated by higher values)										
1 Hidler 2009[110]	RCT – unblinded	Very serious limitation (b)	No serious inconsistency	No serious indirectness	No serious imprecision	62.21 (14.87)	101.96 (15.18)	-39.75 (-46.69, -32.81)	MD 39.75 lower (46.69 to 32.81 lower)	Low
6 minute walk test (m) (6 months follow-up) (>6 month stroke onset^) (Better indicated by higher values)										
1 Hornby 2008[114]	RCTs-single blinded	Very serious limitations (c)	No serious inconsistency	No serious indirectness	Serious imprecision (q)	193 (94)	203 (104)	-10.00 (-59.35, 39.35)	MD 10 lower (59.35 lower to	Very low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Electro-mechanical gait training Mean (SD)/ median (IQR)	Usual care Mean (SD) /median (IQR)	Mean difference (95% CI)	Standardised Mean Difference (SMD) / Mean Difference (MD) (95% CI)	Confidence (in effect)
									39.35 higher)	
6 minute walk test (m) (6 month follow-up) (<60 days stroke onset^) (Better indicated by higher values)										
1 Pohl 2007[209]	RCTs-unclear blinding	Serious limitations (g)	No serious inconsistency	No serious indirectness	Serious imprecision (d)	165.5 (152.5)	112.1 (127.7)	53.40 (9.09, 97.71)	MD 53.40 higher (9.09 to 97.71 higher)	Low
FIM (total score) (post treatment effect) (Better indicated by higher values)										
1 Peurala 2005[204]	RCT - unblinded	Very serious limitations (h)	No serious inconsistency	Serious indirectness	Very serious imprecision (i)	100.9 (12.3)	102.3 (10.9)	-1.40 (-9.72, 6.92)	MD 1.40 lower (9.72 lower to 6.92 higher)	Very low
FIM (total score) (post treatment effect) (Better indicated by higher values)										
1 Tong 2006[260]	RCT – unblinded	Serious limitations (j)	No serious inconsistency	No serious indirectness	(k)	91 (17)	89.5 (26.5)	(l)	(l)	Moderate (k)
FIM (motor items) (post treatment effect) (Better indicated by higher values)										
1	RCT –	Serious	No serious	No serious	Serious	66.9 (15.6)	60.3 (14.8)	6.60 (-	MD 6.6	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Electro-mechanical gait training Mean (SD)/ median (IQR)	Usual care Mean (SD) /median (IQR)	Mean difference (95% CI)	Standardised Mean Difference (SMD) / Mean Difference (MD) (95% CI)	Confidence (in effect)
Schwartz 2009[233]	unblinded	limitations (m)	inconsistency	indirectness	imprecision (n)			0.70, 13.90)	higher (0.70 lower to 13.9 higher)	
Rivermead Mobility Index (post treatment effect) (Better indicated by higher values)										
3 Dias 2007[64] Pohl 2007[209] Hidler 2009[110]	RCTs – 2single blind, 1 unblinded	Very serious limitations (o)	No serious inconsistency	No serious indirectness	No serious imprecision	Change from baseline Dias: -0.35 (0.75) Hidler: 2.0 (0.3) Final values Pohl: 8.5 (3.9)	Change from baseline Dias: -1.26 (1.82) Hidler: 1.6 (0.3) Pohl: 6.3 (3.7)	0.83 (0.35, 1.31)	SMD 0.83 higher (0.35 lower to 1.31 higher)	Low
Rivermead Mobility Index (3 months follow-up) (Better indicated by higher values)										
1 Hidler 2009[110]	RCT – unblinded	Very serious limitations (b)	No serious inconsistency	No serious indirectness	No serious imprecision	2.6 (0.4)	2.2 (0.5)	0.40 (0.19, 0.61)	MD 0.4 higher (0.19 to 0.61 higher)	Low

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Electro-mechanical gait training Mean (SD)/ median (IQR)	Usual care Mean (SD) /median (IQR)	Mean difference (95% CI)	Standardised Mean Difference (SMD) / Mean Difference (MD) (95% CI)	Confidence (in effect)
Rivermead Mobility Index (6 months follow-up) (Better indicated by higher values)										
1 Pohl 2007[209]	RCT – single blinded	Serious limitations (e)	No serious inconsistency	No serious indirectness	No serious imprecision	10.0 (4.1)	7.8 (4.8)	2.20 (0.80, 3.60)	MD 2.20 higher (0.80 to 3.60 higher	Moderate
Barthel Index (post treatment effect) (Better indicated by higher values)										
1 Pohl 2007[209]	RCT – single blinded	Serious limitations (e)	No serious inconsistency	No serious indirectness	No serious imprecision	72.3 (21)	58.7 (21.6)	13.60 (6.89, 20.31)	MD 13.6 higher (6.89 to 20.31 higher)	Moderate
Barthel Index (post treatment effect) (Better indicated by higher values)										
2 Tong 2006[260] Husemann 2007[118]	RCTs- 1 single blinded, 1 unblinded	Serious limitations (jp)	No serious inconsistency	No serious indirectness	(k)	Tong: 84.0 (19) Husmann: 50.0 (25)	Tong: 73.0 (32.5) Husmann: 50 (10)	(l)	(l)	Moderate(k)
Barthel Index (6 months follow-up) (Better indicated by higher values)										
1 Pohl 2007[209]	RCT – single blinded	Serious limitations (a)	No serious inconsistency	No serious indirectness	No serious imprecision	77.5 (23.1)	65.1 (28.0)	12.40 (4.32, 20.48)	MD 12.4 higher (4.32 to	Moderate

Quality assessment						Summary of findings				
								Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Electro-mechanical gait training Mean (SD)/ median (IQR)	Usual care Mean (SD) /median (IQR)	Mean difference (95% CI)	Standardised Mean Difference (SMD) / Mean Difference (MD) (95% CI)	Confidence (in effect)
									20.48 higher)	

(a) Unclear randomisation (Hornby 2008; Peurala 2005), inadequate allocation concealment (Hornby 2008; Pohl 2007; Peurala 2005; Tong 2006), unclear allocation concealment (Hidler 2009) unclear blinding (Hornby 2008), unblinded studies (Peurala 2005; Tong 2006; Hidler 2009) high dropout rate in control group (30%) (Hornby 2008).
(b) Unblinded study with unclear allocation concealment. No ITT analysis. There was a significant difference in age between groups, reported by author. Rivermead Mobility Index at baseline was statistically significantly higher in control group compared to the intervention (Hidler 2009).
(c) Study with unclear blinding and randomisation high dropout rate in control group (30%) (Hornby 2008).
(d) Confidence interval crossed one end of default MID.
(e) Single blinded study with inadequate allocation concealment (Pohl 2007).
(f) 1 unblinded (Peurala 2007), 1 with unclear blinding (Hornby 2008), 2 studies had unclear randomization (Hornby 2008; Peurala 2005) and the majority had inadequate allocation concealment (Hornby 2008; Pohl 2007; Peurala 2005) and unclear allocation concealment (Dias 2007).
(g) Inadequate allocation concealment (Pohl 2007).
(h) Unblinded study with unclear randomization and inadequate allocation concealment (Peurala 2007).
(i) Mean difference did not reach the agreed MID of 22 points.
(j) Study was unblinded with unclear allocation concealment (Tong 2006).
(k) Imprecision could not be assessed because results were reported as median and interquartile range.
(l) Relative and absolute effects could not be calculated because results were reported as median and interquartile range.
(m) Study was not blinded and unclear allocation concealment; Dropout rate greater in intervention group compared to controls (Schwartz 2009).
(n) Mean difference did not reach the agreed MID of 17 points.
(o) Unblinded (Hidler 2009), with one study with inadequate allocation concealment (Pohl 2007) and two studies with unclear allocation concealment (Dias 2007, Hidler 2009).
(p) German version of Barthel Index was used in the study, Husemann et al (2007).
(q) Mean difference did not reach the agreed MID of 28m.

*Walking velocity: 5 and 10 metre timed walk test (post treatment effect): we could not meta-analyse Hidler et al. with other studies as there was substantial heterogeneity (I^2: 99%), therefore the results of this study were presented separately.
^Walking velocity: 5 and 10 metre timed walk test (6 months follow-up): we could not meta-analyse Hornby et al. and Pohl et al. together due to the large difference in time between stroke onset and study entry among the participants.

One RCT (Morone 2012[179]) stratified participants with stroke according to their initial motor impairment levels into separate groups from the outset. Results of this trial are presented in a separate GRADE table since overall values were not provided.

Comparison: Electromechanical gait training versus conventional gait training (in groups stratified by level of motor impairments)

Table 116: GRADE characteristics and clinical summary of findings (Note. LM=low motricity – greater level of impairments; HM= high motricity – lower level of impairment)

Quality assessment						Summary of Findings				
								Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Robotic gait training Means (SD)	Conventional gait training Mean (SD)	Mean difference (95% CI)	Mean difference (MD) (95% CI)	Confidence (in effect)
Functional ambulation classification - Discharge - LM (range of scores: 0-5; Better indicated by higher values)										
Morone 2012[179]	randomised trials (assessor blinded)	Serious (a)	no serious inconsistency	no serious indirectness	no serious imprecision	4 (0.9)	2.1 (1.2)	1.9 (1.05, 2.75)	MD 1.9 higher (1.05 to 2.75 higher)	Moderate
Functional ambulation classification - Follow-up at 2 years - LM (range of scores: 0-5; Better indicated by higher values)										
Morone 2012[179]	randomised trials (assessor blinded)	serious (a)	no serious inconsistency	no serious indirectness	no serious imprecision	4.7 (0.5)	3.1 (1.3)	1.6 (0.81, 2.39)	MD 1.6 higher (0.81 to 2.39 higher)	Moderate
Functional ambulation classification - Discharge - HM (range of scores: 0-5; Better indicated by higher values)										
Morone 2012[179]	randomised trials (assessor blinded)	serious (a)	no serious inconsistency	no serious indirectness	very serious(b)	3.8 (1.1)	3.7 (1.0)	0.1 (-0.74, 0.94)	MD 0.1 higher (0.74 lower to 0.94 higher)	Very Low

Quality assessment						Summary of Findings				
								Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Robotic gait training Means (SD)	Conventional gait training Mean (SD)	Mean difference (95% CI)	Mean difference (MD) (95% CI)	Confidence (in effect)
Functional ambulation classification - Follow-up at 2 years - HM (range of scores: 0-5; Better indicated by higher values)										
Morone 2012[179]	randomised trials (assessor blinded)	serious (a)	no serious inconsistency	no serious indirectness	very serious(b)	4.3 (0.9)	4.0 (1.0)	0.3(-0.46, 1.06)	MD 0.3 higher (0.46 lower to 1.06 higher)	Very Low
Barthel Index - Discharge - LM (range of scores: 0-100; Better indicated by higher values)										
Morone 2012[179]	randomised trials (assessor blinded)	serious (a)	no serious inconsistency	no serious indirectness	no serious imprecision	69.6 (15.1)	52.1 (14.1)	17.5 (5.81, 29.19)	MD 17.5 higher (5.81 to 29.19 higher)	Moderate
Barthel Index - Follow-up at 2 years - LM (range of scores: 0-100; Better indicated by higher values)										
Morone 2012[179]	randomised trials (assessor blinded)	serious (a)	no serious inconsistency	no serious indirectness	no serious imprecision	76.9 (11.5)	64.7 (14.0)	17.5 (5.81, 29.19)	MD 12.2 higher (1.95 to 22.45 higher)	Moderate
Barthel Index - Discharge - HM (range of scores: 0-100; Better indicated by higher values)										
Morone 2012[179]	randomised trials (assessor blinded)	serious (a)	no serious inconsistency	no serious indirectness	very serious(c)	64.2 (21.2)	74.2 (14.1)	-10 (-26.61, 6.61)	MD 10 lower (26.61 lower to 6.61 higher)	Very Low

Quality assessment						Summary of Findings				
								Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Robotic gait training Means (SD)	Conventional gait training Mean (SD)	Mean difference (95% CI)	Mean difference (MD) (95% CI)	Confidence (in effect)
Barthel Index - Follow-up at 2 years - HM (range of scores: 0-100; Better indicated by higher values)										
Morone 2012[179]	randomised trials (assessor blinded)	serious (a)	no serious inconsistency	no serious indirectness	very serious(c)	74.3 (18.7)	77.6 (20.4)	-3.3 (-18.96, 12.36)	MD 3.3 lower (18.96 lower to 12.36 higher)	Very Low
Rivermead Mobility Index - Discharge - LM (range of scores: 0-15; Better indicated by higher values)										
Morone 2012[179]	randomised trials (assessor blinded)	serious (a)	no serious inconsistency	no serious indirectness	no serious imprecision	9.4 (2.7)	4.9 (2.0)	4.5 (2.6, 6.4)	MD 4.5 higher (2.6 to 6.4 higher)	Moderate
Rivermead Mobility Index - Follow-up at 2 years - LM (range of scores: 0-15; Better indicated by higher values)										
Morone 2012[179]	randomised trials (assessor blinded)	serious (a)	no serious inconsistency	no serious indirectness	serious(d)	11.8 (3.5)	7 (3.6)	4.8 (1.96, 7.64)	MD 4.8 higher (1.96 to 7.64 higher)	Low
Rivermead Mobility Index - Discharge - HM (Better indicated by lower values)										
Morone 2012[179]	randomised trials (assessor blinded)	serious (a)	no serious inconsistency	no serious indirectness	serious(e)	7.4 (4.1)	10.1 (4.0)	-2.7 (-5.94, 0.54)	MD 2.7 lower (5.94 lower to 0.54 higher)	Low
Rivermead Mobility Index - Follow-up at 2 years - HM (range of scores: 0-15; Better indicated by higher values)										

Quality assessment						Summary of Findings				
								Effect		
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Robotic gait training Means (SD)	Conventional gait training Mean (SD)	Mean difference (95% CI)	Mean difference (MD) (95% CI)	Confidence (in effect)
Morone 2012[179]	randomised trials (assessor blinded)	serious (a)	no serious inconsistency	no serious indirectness	very serious(b)	10.4 (3.6)	10.6 (3.9)	-0.2 (-3.2, 2.8)	MD 0.2 lower (3.2 lower to 2.8 higher)	Very Low

[a] Unclear allocation concealment, a large proportion (up to 50%) of participants in all study arms did not finish the 4 week treatment.
[b] The confidence interval crosses both default MIDs (0.5 of standard mean difference) ranging from benefit associated with the control treatment to benefit associated with robotic gait training.
[c] The confidence interval crosses both agreed MIDs for the Barthel Index (1.85), i.e. robotic gait training could have positive or negative effects
[d] The confidence interval crosses one default MID (0.5 standard mean difference) from appreciable benefit to no effect associated with robotic gait training
[e]The confidence interval crosses one default MID (0.5 standard mean difference) indicating possible benefit associated with the conventional gait training to no effect.

Narrative summary

The following study is summarised as a narrative because the results were not presented in numerical data that could be included in the GRADE table:

One study [203] randomised 56 patients to gait trainer exercise, walking training and conventional treatment. At the end of 3 weeks training, mean walking velocity (10 metre timed walk test) and walking distance (6 minute walk test) were not different between the gait trainer exercise and walking groups (10 metre timed walk test, p=0.452; 6 minute walk test, p=0.547). The Rivermead Mobility Index improved in all groups (from baseline to end of treatment) but p value for group difference was not statistically significant (p=0.703). Analysis was based on the number of patients who were able to walk 20 minutes (different level of patients' participation in different measurements at different time points) and reconstructed data for 10 metre timed walk test and 6 minute walk test was used; therefore this study was not included in the meta-analysis.

13.9.1.2 Economic evidence

Literature review

No relevant economic evaluations comparing electromechanical gait training with usual care were identified.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

The manufacturers of Lokomat and of Reha-Stim electromechanical gait trainers were contacted and they each supplied costs for their products. The Lokomat electromechanical gait trainer costs ranged between ~£173,000 to ~£264,000 (costs provided by Hocoma by email, 20th June 2011; VAT is excluded). The Reha-Stim electromechanical gait trainer cost was provided but is not reported here as it was deemed commercial in confidence. Assuming a discount rate of 3.5%, a life expectancy for the machine of 10 years, a utilization rate of the machine of 208 days per year and of 4 hours each day, for an intervention consisting of 6 hours of use of the electromechanical gait training, the attributable cost for the intervention using a Lokomat trainer would be between ~£145 and ~£221. To these costs it may be necessary to add personnel costs when the patient needs to be aided in using the electromechanical gait trainer.

13.9.1.3 Evidence statements

Clinical evidence statements

Six studies [114,118,204,209,260,281] of 344 participants found no significant difference in 5 and 10 metre timed walk test (m/sec) between the electromechanical gait training group and the usual care group at the end of the intervention (LOW CONFIDENCE IN EFFECT).

One study [110] of 72 participants found that those who received usual care was associated with a statistically significant improvement in 5 metre timed walk test (m/sec) compared with the electromechanical gait training group at the end of the intervention (LOW CONFIDENCE IN EFFECT).

One study [110] of 72 participants found that those who received usual care was associated with a statistically significant improvement in 5 and 10 metre timed walk test (m/sec) than the electromechanical gait training group, at 3 months follow-up (LOW CONFIDENCE IN EFFECT).

One study [114] of 62 participants (>6 months post-stroke) found no significant difference in 5 and 10 metre timed walk test (m/sec) between the electromechanical gait training group and the usual care group at the end of 6 months follow-up (LOW CONFIDENCE IN EFFECT).

One study [209] of 155 participants (<2 months post-stroke) found that the electromechanical gait training group was associated with a statistically significant improvement in 10 metre timed walk test (self-selected) (m/sec) compared with the usual care group at the end of 6 months follow-up (LOW CONFIDENCE IN EFFECT).

Four studies [64,114,204,209] of 287 participants found no significant difference in 6 minute walk test (m) between the electromechanical gait training and the usual care group at the end of intervention (LOW CONFIDENCE IN EFFECT).

One study [110] of 72 participants found that those who received usual care was associated with a statistically significant greater improvement in 6 minute walk test (m) compared with the electromechanical gait training group at the end of intervention (LOW CONFIDENCE IN EFFECT).

One study [110] of 72 participants found no significant difference in 6 minute walk test (m) (self-selected) between the electromechanical gait training and the usual care group at 3 months follow-up (LOW CONFIDENCE IN EFFECT).

One study [114] of 62 participants (>6 months post-stroke) found no significant difference in 6 minute walk test (m) between the electromechanical gait training and the usual care group at 6 months follow-up (VERY LOW CONFIDENCE IN EFFECT).

One study [209] of 155 participants (<60 days post-stroke) found that those who received electromechanical gait training was associated with a statistically significant greater improvement in 6 minute walk test (m) compared with those who received usual care at 6 months follow-up (LOW CONFIDENCE IN EFFECT).

One study [204] of 30 participants found no significant difference in total Functional Independence Measure between the electromechanical gait training and the usual care group at the end of intervention (VERY LOW CONFIDENCE IN EFFECT).

One study [233] of 67 participants found no significant difference in Functional Independence Measure (Motor item) between electromechanical gait training and usual care at the end of intervention (LOW CONFIDENCE IN EFFECT).

Three studies [64,110,209] of 267 participants found that electromechanical gait training was associated with a statistically significant improvement on the Rivermead Mobility Index compared with the usual care group at the end of intervention (LOW CONFIDENCE IN EFFECT).

One study [110] of 72 participants found that electromechanical gait training was associated with a statistically significant improvement on the Rivermead Mobility Index compared with those who received usual care at 3 months (LOW CONFIDENCE IN EFFECT)

One study [209] of 155 participants found that electromechanical gait training was associated with a statistically significant improvement on the Rivermead Mobility Index compared with those who received usual care at 6 months follow-up (MODERATE CONFIDENCE IN EFFECT).

One study [209] of 155 participants found that electromechanical gait training was associated with a statistically significant improvement on Barthel Index compared with those who received usual care at the end of intervention (MODERATE CONFIDENCE IN EFFECT) and 6 months follow-up (MODERATE CONFIDENCE IN EFFECT).

Electromechanical gait training versus conventional gait training in groups divided by initial motor impairment level

One study[179] of 48 participants found that robotic gait training significantly improved functional ambulatory abilities (as measured by the Functional Ambulation Classification scale) in those with higher levels of motor impairments (at baseline). These improvements were observed both at discharge and at 2 year follow-up compared to conventional gait training. However, these improvements were not observed in participants with fewer impairments (at baseline).

One study[179] of 48 participants found that robotic gait training significantly improved performance in activities of daily living (as measured by the Barthel Index) in those with higher levels of motor impairments (at baseline). These improvements were observed both at discharge and at 2 year follow-up compared to conventional gait training. However, these improvements were not observed in participants with fewer impairments (at baseline).

One study[179] of 48 participants found that robotic gait training significantly improved mobility (as measured by the Rivermead Mobility Index) in those with higher levels of motor impairments (at baseline). These improvements were observed both at discharge and at 2 year follow-up compared to conventional gait training. However, these improvements were not observed in participants with fewer impairments (at baseline).

Economic evidence statements

No cost effectiveness evidence was identified.

13.9.2 Recommendations and link to evidence

	102. Offer electromechanical gait training to people after stroke only in the context of a research study.
Relative values of different outcomes	The outcomes of interest included in the review were walking speed and endurance, the Rivermead Mobility Index and two measures of dependence the Functional Independence Measure, and the Barthel Index. The GDG considered the results of the walking outcomes were of more relevance to the intervention.
Trade-off between clinical benefits and harms	Not applicable. The availability and usage of this equipment is currently extremely limited within the NHS.
Economic considerations	No cost effectiveness studies were identified for this question. The GDG noted that the main cost component for these interventions consists of the cost of acquiring and maintaining the machine, as well as the personnel costs (for example physiotherapist time) that may be required to aid the patient in using the electromechanical gait training. In addition, the GDG noted that there is very limited use of electromechanical gait training devices currently in the UK NHS. Considering the high initial outlay cost for electromechanical gait trainers and the limited evidence for their potential health benefits, the GDG concluded that there was insufficient evidence to conclude that electromechanical gain training represents a cost-effective use of NHS resources.
Quality of evidence	The GDG noted that many of the studies presented had severe to very serious limitations in terms of sample size and study design and there was insufficient evidence to support the use of electromechanical gait training. Many studies did not show a significant difference for the walking speed or capacity outcomes [114,118,204,233,260,281]. In one well designed study by Pohl [209] there is evidence that in patients early after stroke (up to 2 months post stroke) with very poor mobility, who used the electro mechanical gait trainer showed an improvement in walking speed over usual practice which was maintained after 6 months. In addition, patients in the electromechanical gait trainer group showed a clinically significant improvement in Rivermead Mobility Index (post treatment and at 3, 6 months follow-up) and the Barthel Index (6 months follow-up). The recent publication of a study by Morone and colleagues (2012)[179] with a 2 year follow-up showed that robotic gait training improved performance in the Rivermead Mobility and the Barthel index as well as in the Functional Ambulation categories. However, this effect was restricted to those with more severely impaired motor functioning at the outset. It was a small study with 12 participants in each arm and the confidence in effects was very variable ranging from moderate to very low.
Other considerations	The studies examined two different electromechanical gait trainers which vary in design and may feed into different physiological mechanisms. The Lokomat is a driven gait orthosis with electrical drives in knee and hip joints with 4 force transducers with 4 amplifiers that automates locomotion therapy

	on a treadmill. The orthosis is adaptable to subjects' femur length. Reha-Stim is an electromechanical gait trainer with 2 foot plates whose movements simulated stance and swing phases. Step length and walking speed are continuously adjustable by a servo motor. Both use an element of body weight support. Future studies should address the underlying mechanisms of action. This type of intervention is used in some units but not commonly within the UK. There was agreement by the GDG that the evidence, based on two studies (Pohl et al., 2007 and Morone et al., 2012)[209])[179] in favour of the Reha-Stim trainer was not strong enough to make a recommendation for use within the NHS, but that the intervention showed promise and an 'only in research' recommendation should be made.

13.10 Ankle-foot orthoses

An Ankle-Foot Orthosis (AFO) is an appliance designed to support the foot and ankle. After stroke, it is typically prescribed for walking problems where the foot needs to be held up to prevent dragging (foot drop) and/or to give support to the ankle to prevent the leg from collapsing over the foot and ankle in stance. There are many different AFOs, but two common types are those which are rigid which offer greater stability and those that are hinged which offer help with dorsiflexion but less stability at the subtalar joint. AFOs may be custom made or 'off the shelf' and can be made from wide range of different materials. Assessment for use of an AFO should be carried out by an appropriately trained professional. An AFO is an adjunct to therapy and thus should be considered in the context of a comprehensive rehabilitation program with input from a multidisciplinary team.

13.10.1 Evidence review: In people after stroke what is the clinical and cost-effectiveness of Ankle-Foot orthoses of all types to improve walking function versus usual care?

Clinical Methodological Introduction	
Population:	Adults and young people 16 or older who have had a stroke
Intervention:	• All types of orthoses including: • 'Soft and Scotch' casts • Splint • Brace • Low temperature splints • Ankle-Foot Orthosis (AFO) • Ground Reaction Ankle-Foot Orthosis (GRAFO) • Dynamic Ankle-Foot Orthosis (DAFO)
Comparison:	Usual care
Outcomes:	• Walking speed: 6 minute walk test, 10 metre timed walk • Lower limb MAS (stairs) • Walking endurance • Functional Independence Measure (FIM)/ Barthel Index • Rivermead Mobility Index • Cadence • Gait symmetry (stance time, step length) • Quality of Life outcomes

13.10.1.1 Clinical evidence

Searches were conducted for systematic reviews (of randomized controlled trials (RCTs) and cohort studies) and RCTs that compared the effectiveness of all types of ankle-foot orthoses with usual care to improve walking function for adults and young people 16 or older who have had a stroke. Only studies with a minimum sample size of 20 participants (10 in each arm) and including at least 50% of participants with stroke were selected. 5 RCTs (2 parallel and 3 cross-over RCTs) were identified.

Table 117: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix H.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Beckerman 1996 [21]	Stroke patients aged 18-75 years with walking problems caused by a spastic equines or equinovarus position of the foot; at least 4 months post-stroke	Ankle-Foot Orthosis (and placebo thermocoagulation): AFO: Polypropylene AFO was custom made for each patient. AFO in 5° dorsiflexion, corrected for shoe heel height, designed to prevent an equinus or equinovarus position of the foot during walking and inhibit the synergistic extension pattern. Placebo thermocoagulation: needle placed into the tibial nerve, localized and anesthetized with no radiofrequency output. Study duration: 3 months. (N=16)	Placebo Ankle-Foot Orthosis (and placebo thermocoagulation) Placebo AFO: Polypropylene hinged AFO that allows normal range of motion of dorsiflexion and plantar flexion. Placebo thermocoagulation: needle placed into the tibial nerve, localized and anesthetized with no radiofrequency output. (N=14)	• Walking ability measured with the Sickness Impact Profile (SIP) • Walking speed (m/sec)
de Wit 2004 [57]	Stroke patients aged 40-75years, at least 6 months post-stroke.	Walking with plastic, non-articulated Ankle Foot Orthosis (AFO) (3 types: AFO with a small or large posterior steel or with two crossed posterior heel-reinforcements and an open heel) Study duration: at least 6 months. (N=10)	Walking without AFO (N=10)	• Walking speed (cm/sec) • Timed Up and Go (TUG) test (sec) • Stairs test
Erel, 2011[77]	Post-stroke patients of at least 6 months duration (chronic hemi-paretic patients); at a cognitive level to understand the	Dynamic Ankle Foot Orthoses (DAFO) fabricated by a physiotherapist. Fabrication time was 2-3 days on average. DAFO were worn	Control group wore only tennis shoes. (N=16)	• Timed Up and Go Test (sec) • Timed Up Stairs • Timed Down Stairs • Walking speed (m/sec)

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
	aim of the study; were at level 3-5 according to Functional Ambulation Classification; had a maximum spasticity level of 3 according to the Modified Ashworth Scale; had a range of passive dorsiflexion up to at least 90 degrees; were above 18 years old.	inside tennis shoe. Study duration 3 months. (N=16)		
Tyson 2001 [266]	Stroke patients aged over 18 years with hemiplegia (severe impairments)	Hinged AFO made for each patient by an orthotist using 4mm polypropylene with a metal ankle joint and adjustable plantar flexion stop which was set to prevent plantar flexion but allowed full dorsiflexion. Study duration: 1 month. (N=12)	No orthosis. (N=13)	• stride length of Weak and sound leg (cm) • step length of Weak and sound leg (cm) • Step symmetry • Walking speed (m/sec) • Cadence (step/min))
Tyson 2009 [265]	Stroke patients with severe walking problems for ≥2 weeks post-stroke.	Ankle Foot Orthosis (AFO) individually fitted for each patient (N=20)	No device: Walking without the orthosis. (N=20)	• Walking speed (m/sec) • Step length of the weak leg (m)

Comparison: Ankle-Foot Orthosis (AFO) of all types versus usual care

Table 118: Ankle-Foot Orthosis versus usual care- Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
						Dynamic/Ankle-Foot Orthosis		Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Mean (SD)/median (range)	Usual care Mean (SD)/ median (range)	Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
Walking speed (10m walkway) (cm/sec) (patients wore AFO before treatment) (post-treatment effect) (Better indicated by higher values)										
de Wit, 2004[57]	RCT – crossover trial	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	49.6 (24.3)	44.9 (24.0)	4.8 (0.76, 8.84)	MD 4.8 higher (0.76 to 8.84 higher)	Low
Timed up and go (sec) (patients wore AFO before treatment) (post-treatment effect) (Better indicated by lower values)										
de Wit, 2004[57]	RCT – crossover trial	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision (d)	25.6 (11.7)	29.2 (12.9)	-3.6 (-5.59, -1.61)	MD 3.6 lower (5.59 to 1.61 lower)	Low
Stairs test (sec) (patients wore AFO before treatment) (post-treatment effect) (Better indicated by lower values)										
de Wit, 2004[57]	RCT – crossover trial	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision (e)	73.0 (37.8)	81.6 (44.4)	-8.6 (-14.46, -2.74)	MD 8.6 lower (14.46 to 2.74 lower)	Low
Sound Stride length (cm) (1 month follow-up) (Better indicated by higher values)										
Tyson, 2001[266]	RCT – crossover trial	Serious limitations (a)	No serious inconsistency	No serious indirectness	No serious imprecision	39.3 (13.7)	43.8 (14.0)	4.5 (0.91, 8.09)	MD 4.5 higher (0.91 to 8.09 higher)	Moderate
Weak Stride Length (cm) (1 month follow-up) (Better indicated by higher values)										
Tyson, 2001[266]	RCT – crossover trial	Serious limitations (a)	No serious inconsistency	No serious indirectness	No serious imprecision	39.4 (14.3)	44.3 (14.1)	4.9 (1.48, 8.32)	MD 4.9 higher (1.48 to 8.32 higher)	Moderate
Sound step length (cm) (1 month follow-up) (Better indicated by higher values)										

Quality assessment						Summary of findings				
						Dynamic/Ankle-Foot Orthosis	Usual care	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Mean (SD)/median (range)	Mean (SD)/ median (range)	Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
Tyson, 2001[266]	RCT – crossover trial	Serious limitations (a)	No serious inconsistency	No serious indirectness	Very serious imprecision (h)	19.4 (9.9)	20.8 (9.6)	1.40 (- 1.44, 4.24)	MD 1.4 higher (1.44 lower to 4.24 higher)	Very low
Weak step length (cm) (1 month follow-up) (Better indicated by higher values)										
Tyson, 2001[266]	RCT – crossover trial	Serious limitations (a)	No serious inconsistency	No serious indirectness	Very serious imprecision (h)	21.7 (9.5)	23.7 (11.7)	2.0 (- 1.81, 5.81)	MD 2 higher (1.81 lower to 5.81 higher)	Very low
Step Symmetry (1 month follow-up) (Better indicated by higher values)										
Tyson, 2001[266]	RCT – crossover trial	Serious limitations (a)	No serious inconsistency	No serious indirectness	Very serious imprecision (h)	2.6 (4.9)	3.0 (7.8)	0.4 (- 1.34, 2.14)	MD 0.4 higher (1.34 lower to 2.14 higher)	Very low
Cadence (1 month follow-up) (Better indicated by higher values)										
Tyson, 2001[266]	RCT – crossover trial	Serious limitations (a)	No serious inconsistency	No serious indirectness	No serious imprecision	53.1 (16.8)	62.5 (17.2)	9.4 (3.44, 15.36)	MD 9.4 higher (3.44 to 15.36 higher)	Moderate
Walking speed (m/sec) (1 month follow-up) (Better indicated by higher values)										
Tyson, 2001[266]	RCT – crossover trial	Serious limitations (a)	No serious inconsistency	No serious indirectness	Serious imprecision (c)	0.18 (0.1)	0.25 (0.1)	0.07 (0.04, 0.10)	MD 0.07 higher (0.04 to 0.10 higher)	Low
Improvement in Sickness Impact Profile (SIP) ambulation (3 months follow-up) (Better indicated by higher values)										

Quality assessment						Summary of findings				
						Dynamic/Ankle-Foot Orthosis	Usual care	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Mean (SD)/median (range)	Mean (SD)/ median (range)	Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
Beckerman, 1996[21]	RCT – single blind	Serious limitations (b)	No serious inconsistency	No serious indirect-ness	Very serious imprecision (h)	3.23 (-12.8, 13.2)	0.00 (-9.0, 15.8)	2.26 (-3.37, 7.89) (f)	MD 2.26 higher (3.37 lower to 7.89 higher)	Very low
Improvement in SIP physical dimension (3 months follow-up) (Better indicated by higher values)										
Beckerman, 1996[21]	RCT – single blind	Serious limitations(b)	No serious inconsistency	No serious indirect-ness	Very serious imprecision (h)	3.05 (-1.5, 10)	0.84 (-11.2, 8.6)	0.8 (-3.3, 4.90) (f)	MD 0.8 higher (3.3 lower to 4.9 higher)	Very low
Improvement in SIP total score (3 months follow-up) (Better indicated by higher values)										
Beckerman, 1996[21]	RCT – single blind	Serious limitations(b)	No serious inconsistency	No serious indirect-ness	Very serious imprecision (h)	2.52 (-1.9, 10.2)	1.02 (-9.9, 8.1)	2.27 (-1.85, 6.39) (f)	MD 2.27 higher (1.85 lower to 6.39 higher)	Very low
Walking speed- comfortable with shoes (m/sec) (3 months follow-up) (Better indicated by higher values)										
Beckerman, 1996[21]	RCT – single blind	Serious limitations(b)	No serious inconsistency	No serious indirect-ness	Serious imprecision (c)	0.05 (-0.15, 0.17)	-0.01 (-0.07, 0.19)	0.01 (-0.05, 0.07) (f)	MD 0.01 higher (0.05 lower to 0.07 higher)	Low
Walking speed -maximal safe with shoes (m/sec) (3 months follow-up) (Better indicated by higher values)										
Beckerman, 1996[21]	RCT – single blind	Serious limitations(b)	No serious inconsistency	No serious indirect-ness	No serious imprecision	0.04 (-0.33, 0.18)	0.02 (-0.21, 0.87)	0.06 (-0.02, 0.14) (f)	MD 0.06 higher (0.02 lower to 0.14 higher)	Moderate
Timed Up and Go Test (sec) (patients never wore AFO before treatment) (post-treatment effect) (Better indicated by lower values)										
Erel, 2011[77]	RCT-not	Serious limitations	No serious inconsistency	No serious indirectness	Serious imprecisio	14.79(10.36)	19.07 (8.19)	-4.28 (-11.20 to	MD 4.28 lower (11.2 lower to	Low

Quality assessment						Summary of findings				
						Dynamic/Ankle-Foot Orthosis	Usual care	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Mean (SD)/median (range)	Mean (SD)/ median (range)	Mean difference (95% CI)	Mean Difference (MD) (95% CI)	Confidence (in effect)
	blinded	(g)			n (d)			2.64)	2.64 higher)	
Timed Down Stairs (sec) (patients never wore AFO before treatment) (post-treatment effect) (Better indicated by lower values)										
Erel, 2011[77]	RCT-not blinded	Serious limitations (g)	No serious inconsistency	No serious indirectness	Very serious imprecision (h)	13.29 (11.21)	15.36 (8.37)	-2.07 (-9.40 to 5.26)	MD 2.07 lower (9.4 lower to 5.26 higher)	Very low
Timed Up Stairs (sec) (patients never wore AFO before treatment) (post-treatment effect) (Better indicated by lower values)										
Erel, 2011[77]	RCT-not blinded	Serious limitations (g)	No serious inconsistency	No serious indirectness	Serious imprecision (i)	12 (10.21)	15 (7.29)	-3 (-9.57 to 3.57)	MD 3 lower (9.57 lower to 3.57 higher)	Low
Walking speed (m/sec) (patients never wore AFO before treatment) (post-treatment effect) (Better indicated by higher values)										
Erel, 2011[77]	RCT-not blinded	Serious limitations (g)	No serious inconsistency	No serious indirectness	No serious imprecision	0.99 (0.45)	0.72 (0.20)	0.27 (0.01 to 0.53)	MD 0.27 higher (0.01 to 0.53 higher)	Moderate

(a) Randomization not clear.
(b) Inadequate allocation concealment.
(c) Mean difference did not reach the agreed MID of 20cm/sec
(d) Mean difference did not reach the agreed MID of 10 sec
(e) Mean difference did not reach the agreed MID of 15 sec
(f) Results were adjusted for baseline differences with respect to age, period post stroke, and quadriceps strength.
(g) Unblinded, randomisation and allocation concealment not clear
(h) Confidence interval crossed both ends of default MID.
(i) Confidence interval crossed one end of default MID.

Narrative summary

The following study is summarised as a narrative because the results were not presented in numerical data that could be included in the GRADE table:

Tyson, 2009 [265] compared Ankle-Foot Orthosis (AFO) us with no AFO use in a crossover trial. Outcomes reported were functional mobility (measured with the Functional Ambulatory Category [FAC] scores) and walking impairments (walking speed and step length). The study design had serious limitations as there was no clear randomization [NB: The randomisation was the order of the 5 different trial conditions] and the outcome assessors were not blinded. Authors reported that functional mobility improved significantly with AFO use (P =.0001), while the walking impairments were unchanged (mean difference= 0; P [speed (m/s)] = 0.935, P [weak step length (m)] = 0.998. The study included severely impaired acute stroke patients who were not walking outside of Physiotherapy treatments.

13.10.1.2 Economic evidence

Literature review

No relevant economic evaluations comparing Ankle-Foot orthoses with usual care were identified.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

An expert advisor to the GDG provided costs for AFOs similar to the ones in DeWit, 2004 study[57] included in the clinical review (these were pre-fabricated, that is not custom-made):

- AFO with small posterior strut, £30.90 + VAT
- AFO with big posterior strut, £35.54 + VAT
- AFO with two crossed posterior struts, £51.05

Custom made AFOs would be made by a member of specialist multidisciplinary orthotics team and would incur higher costs. In addition, there would be personnel costs related to the time required to fit, trial and adjust the AFO to take into account the specific patient's needs. The GDG has suggested that, in most cases, an orthotist would be performing this task. Adjustments may be made by either orthotists and experienced physiotherapists or occupational therapists (band 6 or 7), depending on the requirements (for example orthotists tend to make permanent and more complex adjustments). The estimated costs range from £45 to £59 per hour of client contact[s].

Evidence statements

13.10.1.3 Clinical evidence statements

One study[57]of 20 participants found that there was a statistically significant improvement in the group with Ankle-Foot Orthosis compared with the usual care group (post-treatment effect) in the following outcomes:

- Walking speed (cm/sec) (LOW CONFIDENCE IN EFFECT)
- Timed Up and Go (TUG) test (sec) (LOW CONFIDENCE IN EFFECT)
- stairs test (LOW CONFIDENCE IN EFFECT)

One study [266]of 25 participants found that the Ankle-Foot Orthosis group was associated with a statistically significant improvement compared with the usual care group at one month in the following outcomes:

- sound and weak stride length (MODERATE CONFIDENCE IN EFFECT)
- cadence (step frequency) (MODERATE CONFIDENCE IN EFFECT)

s Estimated based on data and methods from the Personal Social Services Research Unit 'Unit costs of health and social care' report and Agenda for Change salary bands 6 and 7[51] (typical salary band identified by clinical GDG members). Assumed that an orthotist is costed similar to a physiotherapist.

- walking speed (m/sec) (LOW CONFIDENCE IN EFFECT)

One study [266]of 25 participants found that there was no significant difference between the group with Ankle-Foot Orthosis and the group without Ankle-Foot Orthosis at one month in the following outcomes:

- sound and weak step length (VERY LOW CONFIDENCE IN EFFECT)
- step symmetry (VERY LOW CONFIDENCE IN EFFECT)

One study [21]of 30 participants showed no significant difference between the group with Ankle-Foot Orthosis and the usual care group at 12 weeks in the following outcomes:

- walking ability using Sickness Impact Profile scores: total score (VERY LOW CONFIDENCE IN EFFECT), ambulation (VERY LOW CONFIDENCE IN EFFECT) and physical dimension (VERY LOW CONFIDENCE IN EFFECT)
- walking speed: comfortable with shoes (LOW CONFIDENCE IN EFFECT) and maximal safe, with shoes (m/sec) (MODERATE CONFIDENCE IN EFFECT)

One study[77] of 32 participants found no significant difference between the group with Ankle /Foot Orthoses and the usual care group (post-treatment effect) in the following outcomes:

- Timed Up and Go (TUG) test (sec) (LOW CONFIDENCE IN EFFECT)
- Timed Down Stairs (sec) (VERY LOW CONFIDENCE IN EFFECT)
- Timed Up Stairs (sec) (LOW CONFIDENCE IN EFFECT)

One study[77] of 32 participants showed a statistical significant improvement in the Ankle foot orthoses group compared to the group that received usual care in walking speed (m/sec) (post-treatment effect) (MODERATE CONFIDENCE IN EFFECT)

13.10.1.4 Economic evidence statements

No cost-effectiveness evidence was identified.

13.10.2 Recommendations and link to evidence

	103. Consider ankle–foot orthoses for people who have difficulty with swing-phase foot clearance after stroke (for example, tripping and falling) and/or stance-phase control (for example, knee and ankle collapse or knee hyper-extensions) that affects walking. **104. Assess the ability of the person with stroke to put on the ankle–foot orthosis or ensure they have the support needed to do so.** **105. Assess the effectiveness of the ankle–foot orthosis for the person with stroke, in terms of comfort, speed and ease of walking.** **106. Assessment for and treatment with ankle–foot orthoses should only be carried out as part of a stroke rehabilitation programme and performed by qualified professionals.**

	107. For guidance on functional electrical stimulation for the lower limb see Functional electrical stimulation for drop foot of central neurological origin (NICE interventional procedure guidance 278).
Relative values of different outcomes	Effective AFOs should lead to improvements in walking speed and endurance. A number of factors are important in determining the long term effectiveness of an AFO, including comfort and the ability to put on the AFO easily. Some of the studies considered by the GDG may be regarded as efficacy trials (Tyson,2001[266]) in that they examined immediate benefits and not long term outcomes. Attention needs to be paid to long-term functional outcomes within the home and community.
Trade-off between clinical benefits and harms	No harms were reported in the studies reviewed. The GDG agreed ankle foot orthoses (AFOs) should have a bio-mechanical rationale (to improve function), should be comfortable and well fitted to prevent pain and pressure sores.
Economic considerations	No cost effectiveness studies were identified for this question. The typical cost of AFOs was estimated to be between £30 and £51 depending on the type. Custom made AFOS would cost more. In addition there is some personnel time required to make adjustments for the patient. The GDG considered that in selected patients the additional cost of AFOs, both pre-made and custom made, had the potential to be offset by benefits to the patient in terms of improved function, and therefore improved quality of life. The GDG were aware that limited use is made of many prescribed orthoses with significant cost implications.
Quality of evidence	Three small studies demonstrated that the use of an AFO resulted in a statistically significant effect on velocity at post treatment (de Witt, 2004, Erel, 2011, Tyson, 2001 [77].[57,266]). The study by Erel (2011) demonstrated a clinically significant improvement in walking speed in the ankle foot orthoses group. Confidence in the effects shown for this outcome ranged from very low to moderate due to limitations in study design and the mean difference not reaching the minimal important difference in two of the studies (de Witt 2004 and Tyson 2001[57,266]). It was noted by the GDG that the effects shown in the De Wit study [57] may be underestimated because a flexible AFO was used. In clinical practice a rigid AFO would normally be used if the patient was very immobile. The mobility of the patients within this study was poor therefore for the patient the results may be considered highly clinically significant. In one study (by Beckerman 1996[21]) some participants had already used ankle foot orthoses (AFO's) which may have introduced a bias but it is unclear what direction the bias would effect. The population were stable and walked independently at a median velocity of .32 - .45 m/s, however, there was a large range of walking speeds in each group and no other treatment interventions. Therefore, though the study showed no effect, it is unclear how much difference would be seen with training. The GDG considered the Tyson 2009 study [265] to be one off tests, and although it demonstrated a statistically significant difference in favour of AFO it is unclear how these will translate into home and community settings. The GDG concluded that further research needs to be undertaken to evaluate the use of AFOs in the community setting.
Other considerations	The GDG considered that AFOs are used to support swing phase foot clearance to prevent tripping or falling and stance phase control to

	prevent the ankle of knee collapsing and therefore AFOs should be considered for patients who have these difficulties. The view of the group was that AFO's improve walking speed in selected patients and the studies reviewed demonstrate this. The person would need to be able to put on the AFO themselves or have a family member/carer able to do this for them. The GDG agreed that all stroke units should have access to an orthotics service. AFOs should only be provided after assessment, fitting and trial by an appropriately trained and skilled multi-disciplinary team. Patients should be offered regular review and follow-up to ensure comfort, the appropriateness of the prescription to the individual's day to day requirements and to ensure regular use.

14 Self-care

14.1 Intensity of occupational therapy for personal activities of daily living

Personal Activities of Daily Living (PADLs) are 'those tasks which all of us undertake every day of our lives in order to maintain our level of care' (Hopson, 1981) for example, eating, washing, brushing teeth, and dressing.

A core aspect of Occupational Therapy is the skilled analysis of performance and the impact of physical, sensory, psychological and emotional domains on function. Specific therapeutic goals are then set, and treatment delivered which targets functional performance for example, dressing in the context of the physical, sensory or cognitive impairments. Grading of activities is often a feature of the intervention so that activities increase in complexity as patients develop necessary skills. The theoretical perspective of occupational therapy is twofold, using restorative and compensatory approaches to intervention.

14.1.1 Evidence review: In people after stroke what is the clinical and cost-effectiveness of intensive occupational therapy focused specifically on personal activities of daily living (dressing / others) versus usual care?

Clinical Methodological Introduction	
Population:	Adults and young people 16 or older who have had a stroke
Intervention:	Intensive occupational therapy (OT) - dressing, grooming, bathing, feeding/eating, washing, toileting
Comparison:	Usual care (OT once a week)/no care
Outcomes:	• Nottingham Extended Activities of Daily Living (NEADL) • Extended Activities of Daily Living (EADL) • Functional Independence Measure (FIM) • Barthel Index • Nottingham Stroke Dressing Assessment • Northwick Park Nursing Dependency Scale • Rivermead Mobility Index

14.1.1.1 Clinical evidence

Searches were conducted for systematic reviews and RCTs comparing the clinical and cost effectiveness of intensive occupational therapy focused on personal activities of daily living with usual care or no care in adults or young people of 16 years old or older after stroke. Only studies with a minimum sample size of 20 participants (10 in each arm) were selected. We included seven (7) RCTs.

Table 119 summarises the population, intervention, comparison and outcomes for each of the studies.

Table 119: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix H.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOME
Chiu, 2004[43]	Patients with a stroke who are able to follow	An additional home-based training programme on	Pre-discharge home visit (mean 1.39 visits) but no	• Functional Independence Measure (FIM)

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOME
	instructions and verbally communicate and who are living at home with family support.	bathing devices including at least 2 visits but not more than 3 (mean 2.74) 1st visit : explanation of device and safety; 2nd visit: opportunity to discuss problems using devices and devices checked for fit and safety; 3rd visit: optional, depending on patient's proficiency using device. (N=30)	treatment post-discharge. (N=23)	
Corr, 1995 [48]	First and second stroke patients. (Median number of days since stroke = 50).	Teaching new skills, facilitating independence in activities of daily living, facilitating return of function, enabling patients to use equipment, giving information to patient/carer; referring to or liaising with other agencies. Home visits by an OT after discharge and offered further rehabilitation and reviewed at 2, 8, 16 and 24 weeks. (N=55)	Usual care. (N=55)	• Barthel Index • Nottingham Extended Activities of Daily Living
Gilbertson, 2000 [91]	Patients with a clinical diagnosis of stroke (excluding subarachnoid haemorrhage) without severe cognitive or communication problems.	Domiciliary occupational therapy (OT): 6 week programme (around 10 sessions lasting 30-45 minutes) tailored to recovery goals set by patient (for example regaining self-care or domestic or leisure activities). (N=67)	Inpatient multidisciplinary rehabilitation, pre-discharge home visit for selected patients, support services and equipment, regular review in multidisciplinary stroke clinic and selected patients referred to day hospital. (N=71)	• Barthel Index • Nottingham Extended Activities Daily Living
Logan, 1997 [158]	First time stroke patients discharged from hospital and referred to	Enhanced occupational therapy (OT): equal access to aids and	Usual care; 85 mean minutes per therapy for a mean number of 2.5 visits (N=58).	• Extended Activities of Daily Living(EADL) • Barthel Index

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOME
	occupational therapy department.	budgets for adaptations. Patients seen and treated by a single research OT (sooner than possible with routine service) for a duration of 240 mean minutes per therapy for mean number of 6 visits. (N=53)		
Parker, 2001 [199]	Patients with stroke not more than 6 months without severe illness and no documented history of dementia	Treatment goals: improving independence in self-care tasks such as washing, dressing or bathing. Home occupational therapy (total 10 sessions) lasting not less than 30 minutes each session for up to 6 months (N=156).	No care (N=157).	• Nottingham Extended ADL • Barthel Index
Sackley, 2006 [226]	Participants in residential homes with moderate to severe stroke related disability (BI score 4 to 15) were included.	Aimed at improving independence in personal activities of daily living, such as feeding, dressing, toileting, bathing, transferring and mobilizing. Frequency and duration of therapies was dependent on resident and therapists agreed goals (over 3 months). Median visits per resident per month: 2.7 (range 1-25); time spent with therapist per resident per month 4.5 hours (range 1-10); most sessions lasted around 30 minutes. (N=63)	Usual care (occupational therapist not involved (N=55).	• Barthel Index • Rivermead Mobility Index
Walker, 1999 [278]	Patients with stroke less than 1 month; not been admitted to the hospital; not	Aimed at improving independence in personal and instrumental	No care (N=91).	• Extended Activities of Daily Living (EADL) • Barthel Index

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOME
	living in a nursing or residential home.	activities of daily living. Visits from the occupational therapist for up to 5 months (frequency of visits was agreed between the therapist, patient, and carer). Mean number of visits: 5.8 (SD 3.3, range 1-15). Mean length of each visit was 52 min (11.8, 24-90). (N=94)		

14.1.1.2 Comparison: Intensive occupational therapy focussed on personal activities of daily living versus usual care/no care.

Table 120: Intensive occupational therapy versus usual care/no care - Clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
						Intensive occupational therapy Median (IQR)/Mean (SD)/Frequency (%)	Usual care/no care Median (IQR)/Mean (SD)/ Frequency (%)	Effect		
Authors	Design	Limitations	Inconsistency	Indirectness	Imprecision			Relative Risk/Mean difference (95% CI)	Absolute effect / Mean Difference (MD) (95% CI) or P value	Confidence (in effect)
Functional Independence Measure (3 months follow-up) (Better indicated by higher values)										
Chiu, 2004[43]	RCT- Single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Very serious imprecision (b)	78.6 (7.4)	73.5 (10.9)	5.1 (-0.08 to 10.28)	MD 5.1 higher (0.08 lower to 10.28 higher)	Very low
Barthel Index (2 months follow-up) (Better indicated by higher values)										
Gilbertson, 2000[91]	RCT- single blinded	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision (kd)	1 (0-2)	0 (-3-1)	1 (0.42 to 1.58)	MD 1 higher (0.42 to 1.58 higher)	Low
Barthel Index (3 months follow-up) (Better indicated by higher values)										
Sackley, 2006 [226]	Cluster RCT- Single blinded	Serious limitations(e)	No serious inconsistency	No serious indirectness	No serious imprecision	10.8 (5.5)	8.2 (5.2)	2.6 (0.54 to 4.66)	MD 2.6 higher (0.54 to 4.66 higher)	Moderate
Barthel Index (6 months follow-up) (Better indicated by higher values)										
3 Gilbertson	RCTs- 3 single-blinded, 1	Serious limitations(c	No serious inconsistency	No serious indirectness	Serious imprecision	Gilbertson: 17 (15-19)	Gilbertson: 17 (13-18)	0.59 (-0.55, 1.73)	MD 0.59 higher (0.55	Low

Quality assessment						Summary of findings				
						Intensive occupational therapy Median (IQR)/Mean (SD)/Frequency (%)	Usual care/no care Median (IQR)/Mean (SD)/ Frequency (%)	Effect		
Authors	Design	Limitations	Inconsistency	Indirectness	Imprecision			Relative Risk/Mean difference (95% CI)	Absolute effect / Mean Difference (MD) (95% CI) or P value	Confidence (in effect)
, 2000[91]; Walker, 1999[278] Sackley, 2006 [226]	Cluster RCT	)			(d)	Walker: 20 (18-20) Sackley (changes): - 0.3 (4.2)	Walker: 18 (16-20) Sackley (changes): - 2.1 (3.7)		lower to 1.73 higher)	
Barthel Index (6 months follow-up) (Better indicated by higher values)										
Logan, 1997 [158]	RCT- Single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	(f)	16 (1-20)	16 (2-20)	(g)	(g)	Moderate (f)
Barthel Index (6 months follow-up) (Better indicated by higher values)										
Parker, 2001 [199]	RCT- Single blinded	Serious limitations(c)	No serious inconsistency	No serious indirectness	(f)	18 (15-20)	17 (15-20)	(g)	(g)	Moderate (f)
Barthel Index (score <12) (1 year follow-up) (Better indicated by higher values)										
Corr, 1995 [48]	RCT- Single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Very serious imprecision (m)	22/55 (40%)	22/55 (40%)	1 (0.63 to 1.58)	0 fewer per 1000 (from 148 fewer to 232 more)	Very low
Barthel Index (1 year follow-up) (Better indicated by higher values)										
Parker, 2001 [199]	RCT- Single blinded	Serious limitations(c)	No serious inconsistency	No serious indirectness	(f)	17 (14-19)	17 (14-20)	(g)	(g)	Moderate (f)

Quality assessment						Summary of findings				
						Intensive occupational therapy Median (IQR)/Mean (SD)/Frequency (%)	Usual care/no care Median (IQR)/Mean (SD)/ Frequency (%)	Effect		
Authors	Design	Limitations	Inconsistency	Indirectness	Imprecision			Relative Risk/Mean difference (95% CI)	Absolute effect / Mean Difference (MD) (95% CI) or P value	Confidence (in effect)
Nottingham Extended Activities of Daily Living (total) (2 months follow-up) (Better indicated by higher values)										
Gilbertson, 2000 [91]	RCT	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision (i)	27 (19-43)	23 (11-35)	4 (-0.43 to 8.43)	MD 4 higher (0.44 lower to 8.44 higher)	Low
Nottingham Extended Activities of Daily Living (total) (6 months follow-up) (Better indicated by higher values)										
2 Parker, 2001 [199] Gilbertson, 2000 [91]	RCTs- Single blinded	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision (i)	Parker: 28 (15-38) Gilbertson: 34.7 (18.4)	Parker: 21 (14-38) Gilbertson: 33.1 (18.9)	3.41 (0.00, 6.82)	MD 7 higher (12.37 lower to 26.37 higher)	Low
Nottingham Extended Activities of Daily Living (total) (1 year follow-up) (Better indicated by higher values)										
Parker, 2001 [199]	RCT- Single blinded	Serious limitations(c)	No serious inconsistency	No serious indirectness	Serious imprecision (i)	34.1 (19.1)	33.3 (19.5)	0.8 (-4.32 to 5.92)	MD 0.8 higher (4.32 lower to 5.92 higher)	Low
Nottingham Extended Activities of Daily Living (not able to feed) (1 year follow-up) (Better indicated by higher values)										
Corr, 1995 [48]	RCT- Single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision (j)	11/55 (20%)	19/55 (34.5%)	0.58 (0.3 to 1.1)	145 fewer per 1000 (from 242 fewer to 35 more)	Low
Nottingham Extended Activities of Daily Living (Not able to use the telephone) (1 year follow-up) (Better indicated by higher values)										

Quality assessment						Summary of findings				
						Intensive occupational therapy	Usual care/no care	Effect		
Authors	Design	Limitations	Inconsistency	Indirectness	Imprecision	Median (IQR)/Mean (SD)/Frequency (%)	Median (IQR)/Mean (SD)/ Frequency (%)	Relative Risk/Mean difference (95% CI)	Absolute effect / Mean Difference (MD) (95% CI) or P value	Confidence (in effect)
Corr, 1995 [48]	RCT- Single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	Serious imprecision (j)	16/55 (29.1%)	29/55 (52.7%)	0.55 (0.34 to 0.89)	237 fewer per 1000 (from 58 fewer to 348 fewer)	Low
Nottingham Extended Activities of Daily Living (total) (1 year follow-up) (Better indicated by higher values)										
Corr, 1995 [48]	RCT- Single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	(f)	3 (0-20)	2 (0-21)	(g)	(g)	Low (f)
Extended Activities of Daily Living (total) (3 months follow-up) (Better indicated by higher values)										
Logan, 1997 [158]	RCT- Single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	(f)	8 (0-19)	3 (0-18)	(g)	P<0.01(g) (h)	Moderate (f)
Rivermead Mobility Index (3 months follow-up) (Better indicated by higher values)										
Sackley, 2006 [226]	Cluster Randomised Trial- Single blinded	Serious limitations(e)	No serious inconsistency	No serious indirectness	No serious imprecision	5.2 (3.7)	3.5 (3.1)	1.7 (0.40 to 3.00)	MD 1.7 higher (0.4 to 3 higher)	Moderate
Rivermead Mobility Index (6 months follow-up) (Better indicated by higher values)										
Sackley, 2006 [226]	Cluster Randomised Trial- Single blinded	Serious limitations(e)	No serious inconsistency	No serious indirectness	Very serious imprecision (l)	4.5 (3.5)	3.4 (2.7)	1.1 (-0.20 to 2.4)	MD 1.1 higher (0.2 lower to 2.4 higher)	Very low

Quality assessment						Summary of findings				
						Intensive occupational therapy	Usual care/no care	Effect		
Authors	Design	Limitations	Inconsistency	Indirectness	Imprecision	Median (IQR)/Mean (SD)/Frequency (%)	Median (IQR)/Mean (SD)/ Frequency (%)	Relative Risk/Mean difference (95% CI)	Absolute effect / Mean Difference (MD) (95% CI) or P value	Confidence (in effect)
Extended Activities of Daily living (6 months follow-up) (Better indicated by higher values)										
Walker, 1999 [278]	RCT- Single blinded	Serious limitations(c)	No serious inconsistency	No serious indirectness	No serious imprecision	16 (11-18.75)	12 (6-17)	3 (0.78 to 5.22)	MD 3 higher (0.78 to 5.22 higher)	Moderate
Extended Activities of Daily Living (total) (6 months follow-up) (Better indicated by higher values)										
Logan, 1997 [158]	RCT- Single blinded	Serious limitations(a)	No serious inconsistency	No serious indirectness	(f)	8 (0-21)	6 (0-18)	(g)	(g) (k)	Moderate (f)

[a] Unclear randomisation and allocation concealment.
[b] Mean difference did not reach the agreed MID of 17 points.
[c] Unclear blinding
[d] Mean difference did not reach the agreed MID of 1.85 points.
[e] Unclear allocation concealment
[f] Imprecision could not be assessed because only median and interquartile ranges of data reported
[g] Relative/Absolute effect could not be estimated because only median and interquartile ranges of data reported
[h] P value as reported by the authors.
[i] Confidence interval crosses the lower limit of specified MID (-0.9)
[j] Confidence interval crosses one end of the default MID (0.75).
[k] Authors reported no significant difference between the intensive occupational therapy group and usual care group.
[l] Confidence interval crossed both ends of default MID.
[m] Confidence interval crosses both ends of default MID (0.75 to 1.25)

14.1.1.3 Economic evidence

Literature review

No relevant economic evaluations comparing intensive occupational therapy with usual care were identified.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

The GDG noted that the main difference in terms of resources between intensive therapy and usual care was the time occupational therapists would spend with patients.

The estimated cost per hour of client contact[t] for a band 6 occupational therapist is £45 (hospital-based) or £48 (community-based). The GDG also noted that to these costs it may be necessary to add the cost of additional specific aids (such as bars used to facilitate the use of bathrooms) that can be used in these interventions.

14.1.1.4 Evidence statements

Clinical evidence statements

One study[43] comprising 53 participants found no significant difference in Functional Independence Measure at 3 months after stroke between the group that received intensive occupational therapy and the usual care group (VERY LOW CONFIDENCE IN EFFECT).

One study[91] comprising 138 participants found a significant difference in the Barthel Index at 2 months in favour of the group that received intensive occupational therapy compared to the usual care group, although this difference was not of clinical importance (LOW CONFIDENCE IN EFFECT).

One study[226] comprising 118 participants found a significant difference in the Barthel scores at 3 months after stroke in favour of the group that received intensive occupational therapy compared to the usual care group (MODERATE CONFIDENCE IN EFFECT).

Three studies[91,226,278] comprising 441 participants found no significant difference in the Barthel Index at 6 months follow-up by the group receiving intensive occupational therapy compared to the usual care group (LOW CONFIDENCE IN EFFECT).

One study[48] comprising 110 participants found no significant difference in the proportion of participants achieving less than 12 in Barthel scores at 1 year after stroke between the group that received intensive occupational therapy and the usual care group (VERY LOW CONFIDENCE IN EFFECT).

One study[91] comprising 138 participants found no significant difference in the Nottingham Extended ADL scores at 2 months between the group that received intensive occupational therapy and the usual care group (LOW CONFIDENCE IN EFFECT).

t Estimated based on data and methods from the Personal Social Services Research Unit 'Unit costs of health and social care' report and Agenda for Change salary band 6[51] (typical salary band identified by clinical GDG members).

Two studies [91,199] comprising 451 participants found no significant difference in the Nottingham Extended ADL scores at 6 months after stroke between the group that received intensive occupational therapy and the usual care group (LOW CONFIDENCE IN EFFECT).

One study[199] comprising 313 participants found no significant difference in the Nottingham Extended ADL scores at 12 months after stroke between the group that received intensive occupational therapy and the usual care group (LOW CONFIDENCE IN EFFECT).

One study[48] comprising 110 participants found no significant difference in the proportion of participants able to feed themselves as measured by the Nottingham Extended Activities of Daily Living scale at 1 year after stroke in the intensive occupational therapy group compared to the usual care group (LOW CONFIDENCE IN EFFECT).

One study[48] comprising 110 participants showed that a significantly higher proportion of participants in the intensive occupational therapy group were able to use the telephone as measured by the Nottingham Extended Activities of Daily Living scale at 1 year after stroke compared to the usual care group (LOW CONFIDENCE IN EFFECT).

One study[226] comprising 118 participants found a significant difference in the Rivermead mobility scores at 3 months follow-up in favour of the group that received intensive occupational therapy compared to the usual care group (MODERATE CONFIDENCE IN EFFECT).

One study[226] comprising 118 participants found no significant difference in the Rivermead mobility scores at 6 months follow-up between the group that received intensive occupational therapy and the usual care group (VERY LOW CONFIDENCE IN EFFECT).

One study[278] comprising 185 participants found a significant difference in the Extended Activities of Daily Living scores at 6 months follow-up in favour of the group that received intensive occupational therapy compared to the usual care group (MODERATE CONFIDENCE IN EFFECT).

Economic evidence statements

No cost-effectiveness evidence was identified.

14.1.2 Recommendations and Link to Evidence

	108. Provide occupational therapy for people after stroke who are likely to benefit, to address difficulties with personal activities of daily living. Therapy may consist of restorative or compensatory strategies. • **Restorative strategies may include:** - **encouraging people with neglect to attend to the neglected side** - **encouraging people with arm weakness to incorporate both arms** - **establishing a dressing routine for people with difficulties such as poor concentration, neglect or dyspraxia which make dressing problematic.** • **Compensatory strategies may include:** - **teaching people to dress one-handed** - **teaching people to use devices such as bathing and**

	dressing aids. **109. People who have difficulties in activities of daily living after stroke should have regular monitoring and treatment by occupational therapists with core skills and training in the analysis and management of activities of daily living. Treatment should continue until the person is stable or able to progress independently.** **110. Assess people after stroke for their equipment needs and whether their family or carers need training to use the equipment. This assessment should be carried out by an appropriately qualified professional. Equipment may include hoists, chair raisers and small aids such as long-handled sponges.** **111. Ensure that appropriate equipment is provided and available for use by people after stroke when they are transferred from hospital, whatever the setting (including care homes).**
Relative values of different outcomes	The outcomes included in the review were: Functional Independence Measure, Barthel Index, Nottingham Extended ADL Index, Extended Activities of Daily Living Scale and Rivermead Mobility Index, The GDG considered the studies that reported FIM (Motor subscale) and Barthel outcomes to be the most useful for assessing functional outcomes.
Trade-off between clinical benefits and harms	Provided the intervention is delivered by an appropriately trained Occupational Therapist the GDG did not consider there to be any significant harms associated with this type of intervention and that the benefits gained by being able to participate in activities of daily living were significant in terms of patients' quality of life. The GDG agreed that therapies should include both a restorative approach (aiming to regain function) and a compensatory (use of aids and equipment) approach to help an individual compensate for residual impairments. Appropriate equipment needs to be provided to stroke patients once discharged from hospital, whatever the setting they are discharged to, including nursing homes. This provision would ideally be following assessment by an Occupational Therapist and may include practice and training with equipment.
Economic considerations	No cost-effectiveness studies were found for this question. Occupational therapy is currently routinely provided to stroke patients. Delivering more intensive intervention would require higher personnel input, and possibly more equipment, hence more resources would be needed. However, these may be offset by a reduction in social and health-funded care packages and improvements in patients' quality of life.
Quality of evidence	The GDG recognised that most of the studies were community based and therefore have applicability to early supported discharge and to the long-term management of stroke. It was noted that the patient population in the Sackley study, 2006 was different from the other studies as they were older and in residential nursing homes (these patients were seen to maintain performance in comparison with control group, who deteriorated). The GDG also

	considered that management of patients had changed since the publication of the Walker study [278] as these patients had not been admitted to hospital, however it was useful and it may reflect a population who would now receive early supported discharge as they scored higher on the Barthel index at baseline. The GDG considered the studies included in the review to be feasibility studies. Confidence in the effect shown in most of the outcomes were low to moderate due to limitations in study design (unclear randomisation and allocation concealment) and imprecision around the effect estimate. Although it was found that there was a clinically significant effect of intensive OT in Barthel Index at 3 months compared to usual care group (Sackley 2006 [226]) and the confidence on this effect was moderate, this effect was not preserved at six months follow-up. The Parker study [199] was the only large multi-centred, RCT, however this produced equivocal results. The inclusion of this data in a meta-analysis [151] (which included studies with smaller numbers than included in this clinical review) has shown that there was significant benefit shown in the intensive arm of occupational therapy. Overall the GDG agreed studies showed short-term functional gain at 3 months but not over a longer term. Some limited evidence showed that functional gains are maintained at 6 months and 1 year in the intensive OT groups (Gilbertson 2000,Sackley 2006,Walker 1999 [91,226,278]) The GDG agreed that from the evidence available for those patients with stroke who are managed within the community, occupational therapy provides some benefit, but there is currently no evidence for those patients with moderate stroke who are managed in the acute (hospital) setting and further research is required. The GDG considered that the patients included in the studies tended to be those with moderate stroke and physically fitter, therefore treatment within the community rather than in hospital would be appropriate for this particular population, but would not be applicable for all stroke patients.
Other considerations	The GDG recognised that defining intensity is challenging and can be defined in terms of frequency of treatment, total amount of treatment, duration of treatment, or mode of delivery. The amount of occupational therapy mentioned in the reviewed studies varied but was typically less than the current (5 session x 45 minutes per week) recommended in the current NICE Quality standards. The studies identified gave little indication how much occupational therapy is needed but did indicate that occupational therapy is effective. The GDG noted that the description of occupational therapy interventions was limited within the studies reviewed, but they did employ a range of restorative and compensatory strategies. Consensus recommendations were made to reflect this and examples of the types of interventions delivered were indicated.

15 Community participation and long term recovery

At some point after the onset of stroke, no further changes can reasonably be expected at the impairment level, however changes can still be made in terms of reintegration into an individual's family, social and community life Rehabilitation services should aim to withdraw only when people with stroke have the knowledge, skills and if necessary the support they need to manage this process. This chapter focusses on self-management, long term health and social support and return to the work place.

A search for systematic review evidence for the topic of long term health and social support of the person after stroke. There was no evidence identified and therefore recommendations were based on modified Delphi consensus statements that were drawn up based on recommendations in published national and international guidelines – see Appendix F for details.

15.1 Return to work

Work contributes to adult identity, confers financial benefits and status, and can improve quality of life and reduces ill health. The Stroke Strategy[61] highlighted the need for people who have had a stroke and their carers to be enabled to participate in paid, supported and voluntary employment. The National Service Framework for people with long term (neurological) conditions [60] identified the need individuals may have for vocational rehabilitation offered by local or specialist rehabilitation services to: enter training or work opportunities; remain in or return to their existing job; identify and prepare for suitable alternative work options; plan withdrawal from work at an appropriate time (conserving pension and other rights); and access appropriate alternative occupational and educational opportunities.

Vocational rehabilitation is often delivered by health professionals, linked to community rehabilitation services and aims to review and optimise the skills required to engage in meaningful occupation, which might be paid or voluntary and may or may not be the role they were employed in prior to their stroke. Ideally specialist vocational rehabilitation services are both multidisciplinary and multi-agency (with rehabilitation services working alongside Job Centre Plus), but in practice most vocational rehabilitation is delivered by occupational therapists and psychologists based in community rehabilitation teams.

Interventions are most effective when they are tailored to the individual's impairments in the context of the demands of the work place. They may include the use of memory strategies, computer use, confidence building, planning and pacing, as well as liaising with employers regarding education on stroke specific issues, reasonable accommodations and graded return to work activities.

15.1.1 Evidence Review: In people after stroke what is the clinical and cost-effectiveness of interventions to aid return to work versus usual care?

Clinical Methodological Introduction	
Population:	Adults and young people 16 or older who have had a stroke
Intervention:	• Job retention • Return to work (tailored to the impairment of the patient recognising the demands of the job)
Comparison:	Usual care (nothing)
Outcomes:	• Same job same employer • Same job different employer

Clinical Methodological Introduction	
	• Different job same employer • Different job different employer • Unemployment • Retired due to ill health • Voluntary work • Benefit claims

15.1.2 Clinical evidence

Searches were conducted for systematic reviews and RCTs comparing interventions to aid return to work with usual care for adults or young people of 16 years old after stroke. Only studies with a minimum sample size of 20 participants (10 in each arm) and including at least 50% of participants with stroke were selected. One RCT was identified. This study was conducted in a mixed population of participants with acquired brain injury, of whom 59.1% had experienced stroke.

Table 121: Summary of studies included in the clinical evidence review. For full details of the extraction please see Appendix H.

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
Trexler 2010[262]	Patients with acquired brain injury (traumatic brain injury (31.8%), intracranial haemorrhage (31.8%), stroke (27.3%), other (13.6%)) aged between 18-60 years. Participants had been employed and/or attended school for 2 years prior to the injury and had a goal to return to work or to school.	Resource facilitation intervention to return to work (duration 6 months) including assessment of patient's current status, needs and resources, plan and document mutually agreed upon needs, identification of community resources for services and supports, facilitation of access to resources through education and advocacy, proactively monitoring of the status of the plan through telephone, internet and personal contacts with patient or caregiver at a minimum of every 2 weeks and provision of education (information on the injury, personal advocacy and partnership development) with the patient or caregiver. Former employer was involved through education, titrating	Usual care: patients received only recommended services by their healthcare providers (outpatient rehabilitation therapies, neuropsychological services, medical follow-up). No contact during the 6 months follow-up by a resource facilitator was made. (N=11)	• Full time employment • Part time employment • Employment • Unemployment

STUDY	POPULATION	INTERVENTION	COMPARISON	OUTCOMES
		return to work schedules and facilitating utilization of job supports. (N=12)		

Comparison of resource facilitation intervention for return to work versus usual care

Table 122: Resource facilitation intervention for return to work versus usual care - clinical study characteristics and clinical summary of findings

Quality assessment						Summary of findings				
						Resource facilitation Frequencies (%)	Usual care Frequencies (%)	Effect		
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision			Relative Risk (95% ci)	Absolute effect (95% CI)	Confidence (in effect)
Full time employment										
1 Trexler 2010[262]	RCT-unblinded	Very serious limitations (a)	No serious inconsistency	Serious indirectness (b)	Very serious imprecision (c)	4/12 (33.3%)	3/11 (27.3%)	1.22 (0.35 to 4.28)	60 more per 1000 (from 177 fewer to 895 more)	Very low
Part time employment										
1 Trexler 2010[262]	RCT-unblinded	Very serious limitations (a)	No serious inconsistency	Serious indirectness (b)	Very serious imprecision (c)	3/12 (25%)	1/11 (9.1%)	2.75 (0.33 to 22.69)	159 more per 1000 (from 61 fewer to 1972 more)	Very low
Any employment										
1 Trexler 2010[262]	RCT-unblinded	Very serious limitations (a)	No serious inconsistency	Serious indirectness (b)	Very serious imprecision (c)	7/12 (58.3%)	4/11 (36.4%)	1.6 (0.64 to 4.01)	7218 more per 1000 (from 131 fewer to 1095 more)	Very low
Unemployment										
1 Trexler 2010[262]	RCT-unblinded	Very serious limitations (a)	No serious inconsistency	Serious indirectness (b)	Very serious imprecision (c)	5/12 (41.7%)	7/11 (63.6%)	0.65 (0.29 to 1.46)	223 fewer per 1000 (from 452 fewer to 293 more)	Very low

(a) Unblinded study. No details on randomization and unclear allocation concealment.
(b) Patients had experienced traumatic brain injury (TBI) with no mention on the phase of their illness. 59.1% participants had stroke.
(c) Confidence interval crossed both ends of default MID (0.75, 1.25)

Narrative summary

The following study is summarised as a narrative because the results were not presented in numerical data that could be included in the GRADE table:

The authors of the once included study [262] also reported that the distribution of the three categories (full-time, part-time and unemployed) of the employment item of the Mayo-Portland Adaptability Inventory-4 Participation Index (M2PI) were significantly different between the resource facilitation intervention group and the usual care (P< 0.0001).

15.1.2.1 Economic evidence

Literature review

No relevant economic evaluations comparing occupational therapy to aid return to work with usual care were identified.

Intervention costs

In the absence of cost-effectiveness analysis for this review question, the GDG considered the expected differences in resource use between the comparators and relevant UK NHS unit costs. Consideration of this alongside the clinical review of effectiveness evidence was used to inform their qualitative judgement about cost effectiveness.

The GDG considered that typically a band 7 community occupational therapist would deliver this service. The estimated cost per hour of client contact is £59[u]. Typical resource use per patient was estimated to be in the range of 9 to 15 hours.

15.1.2.2 Evidence statements

Clinical evidence statements

One study[262] comprising of 23 participants showed that there was no significant difference in the proportion of participants returning to full time employment between those who received resource facilitator intervention and the usual care group (VERY LOW CONFIDENCE IN EFFECT).

One study[262] comprising of 23 participants showed that there was no significant difference in the proportion of participants returning to part time employment between those who received resource facilitator intervention and the usual care group (VERY LOW CONFIDENCE IN EFFECT).

One study[262] comprising of 23 participants showed that there was no significant difference in the proportion of participants returning to employment between those who received resource facilitator intervention and the usual care group (VERY LOW CONFIDENCE IN EFFECT).

One study[262] comprising of 23 participants showed that there was no significant difference in the proportion of unemployed participants between those who received resource facilitator intervention to aid to return work and to the usual care group (VERY LOW CONFIDENCE IN EFFECT).

Economic evidence statements

No cost effectiveness evidence was identified.

15.1.3 Recommendations and link to evidence

	112. Return-to-work issues should be identified as soon as possible after the person's stroke, reviewed regularly and managed actively. Active management should include: • **identifying the physical, cognitive, communication and psychological demands of the job (for example, multi-tasking by answering emails and telephone calls in a busy office)**

u Estimated based on data and methods from Personal Social Services Research Unit 'Unit costs of health and social care' report and Agenda for Change salary band 7[51] (typical salary band identified by clinical GDG members).

	• **identifying any impairments on work performance (for example, physical limitations, anxiety, fatigue preventing attendance for a full day at work, cognitive impairments preventing multi-tasking, and communication deficits)** • **tailoring an intervention (for example, teaching strategies to support multi-tasking or memory difficulties, teaching the use of voice-activated software for people with difficulty typing, and delivery of work simulations)** • **educating about the Equality Act 2010[v] and support available (for example, an access to work scheme)** • **workplace visits and liaison with employers to establish reasonable accommodations, such as provision of equipment and graded return to work.** **113. Manage return to work or long-term absence from work for people after stroke in line with recommendations in Managing long-term sickness and incapacity for work (NICE public health guidance 19).**
Relative values of different outcomes	Return to work was the only outcome considered in this review. The GDG noted the National Stroke Strategy which states that people should be encouraged in their participation roles [61] and commented that vocational rehabilitation programmes may enable an individual to improve the structure to their day and engage in meaningful occupation while not returning to work. This may make a difference in terms of improving the quality of life for the patient and their carers. However, if people do not return to work the therapy can be regarded as a failure despite resulting in greater participation in social roles. The GDG acknowledged that other participation roles are as important as return to work and suggested that future studies should record HrQoL and participation outcomes. The GDG agreed that work is one of a range of participation roles which needs to be considered, in a comprehensive rehabilitation programme.
Trade-off between clinical benefits and harms	Many of the disabilities that prevent return to work are not obvious such as: low self-esteem, low confidence, cognitive impairments, fatigue, low mood and depression, and treatment of these difficulties can have a significant impact not only on the ability to return to work but more generally on quality of life [32,33].
Economic considerations	No published studies were identified assessing cost or cost-effectiveness. The estimated cost of occupational therapy to aid return to work was estimated to be in the range of £531 to £885 per patients. The GDG considered that the additional cost of the intervention may be offset by the potential increase in patient and carer quality of life.
Quality of evidence	This was a small underpowered RCT with a mixed population (acute brain injury) with 59.1% of the participants had had a stroke. Although the study described a mixed population of acute brain injury including ischaemic stroke and intracerebral haemorrhage, the GDG agreed that in principle the

[v] HM Government (2010) Equality Act [online]

	intervention may be transferable to a stroke population provided the impairments in the different pathological groups were similar. However, the range of impairments was not clearly described. The group also noted that from the limited description given of the intervention it would be difficult to reproduce in other studies. Confidence in the effect for the return to work outcomes (full time, part time employment, any employment, unemployment) was very low. The GDG was not confident in the results presented because of the study limitations (unblinded with unclear randomization and allocation concealment). However the GDG noted there are serious problems on planning (including agreed blinding), recruiting, conducting and analysing RCTs of this sort. The GDG agreed that because of these difficulties there would be very few studies looking at interventions for return to work. In contrast, there are a large number of papers synthesising consensus narratives of what needs to be done but little RCT or health economic evidence that would promote the commissioning of this type of intervention. The group had wished to ascertain whether RCT or economic evidence was available and this review has answered that question.
Other considerations	The consensus view held by the GDG was that returning to work after stroke was clearly the best outcome for an individual of working age and this study provides one example of an intervention to aid return to work. The GDG considered that identifying needs and any obstacles to returning to work should be explored as soon as possible in order to plan reintegration back into the workplace. Because of the lack of evidence there is no systematic way of assessing people on their capacity for work, which components of a vocational intervention work or what the duration of an intervention should be. Future studies need to be conducted to ascertain what does and doesn't work in this field. The GDG recognised the importance of the Equal Opportunities Act in creating an environment in which patients are supported to return to work. The GDG recognised the national consensus that exits around the key elements of vocational rehabilitation, namely analysis of the impairment, the demands of the job, education of the patient, tailored interventions, work place visits and establishing workplace accommodations. Although identified as an important intervention within the Stroke Strategy and the National Service Framework for long term (neurological) conditions, the GDG agreed that there is limited resource to deliver vocational rehabilitation interventions within the NHS. The GDG formulated consensus recommendations based on discussion of current practice of interventions in their own rehabilitation services and knowledge of other national guidance in this area. The group were in agreement that this was an area where provision needed to improve and therefore directive recommendations were drafted. The GDG agreed that services need the capacity to deliver vocational rehabilitation to people with neurological impairments such a stroke. The group recognised that many working age patients have vocational needs which are unmet, often leading to job loss. The group noted that it is the resilience of the patient and willingness of the employer to support the individual which will determine whether a person returns to work or not. The group agreed that more data needs to be collected on the number of people who return to work after stroke. Randomised controlled trials of the training needs of health professionals delivering vocational rehabilitation would be an area where further research is needed. The GDG acknowledged that health professionals receive very little training in this area.

	It was noted that other NICE guidance available on return to work is available: Managing long-term sickness absence and incapacity for work (NICE public health guidance 19). Research needs to be undertaken to establish the structural processes that allow effective inter-agency work.

15.2 Long term health and social support

There was a lack of direct evidence for this topic. Therefore recommendations in this section were based on the modified Delphi consensus statements that were drafted from recommendations of published national and international guidelines. We provide tables of statements that reached consensus and statements that did not reach consensus and give a summary of how they were used to draw up the recommendations. For details on the process and methodology used for the modified Delphi survey see Appendix F.

15.2.1 What ongoing health and social support do the person after stroke and their carer(s) require to maximise social participation and long term recovery?

Population	Adults and young people 16 or older who have had a stroke
Components	• Continued monitoring and re-access into rehab • Long term support/care at home • Social participation activities • Carer/family support & education
Outcomes	• Patient and carer satisfaction • Quality of life • optimised strategies to minimise impairment and maximise activity/participation

15.2.2 Delphi statements where consensus was achieved

Table 123: Table of consensus statements, results and comments (percentage in the results column indicates the overall rate of responders who 'strongly agreed' with a statement and 'amount of comments' in the final column refers to rate of responders who used the open ended comments boxes, i.e. No. people commented / No. people who responded to the statement)

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
	If there is a new identified need for further stroke rehabilitation services, the person who has had a stroke should be able to self-refer with the support of a GP or specialist community services.	66.7	In round 2 - 23/99 (23%) panel members commented; 11/81(14%) in round 3: One issue that was highlighted is the demand this may create ("Direct self-referral could lead to demand outstripping resources of the stroke rehabilitation service. There does need to be an assessment.").

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
			Other panel members thought that the phrase 'with the support of' was unclear since this would not mean self-referral anymore. "we operate self-referral for anyone previously known to the stoke service". " this is unclear, how can you self-refer with the support of a GP, are they still being gatekeepers then?"
	Focus on life after stroke may include: Information and discussion about community access Participation in community activities Social roles Information about driving Opportunities to discuss issues around sexual function	 75.2 72.9 70.2 76.4 68.2	In round 2 - 10/98 (10%) panel members commented; 37/85(44%) in round 3 (direct prompt given in round 3): A few other areas of focus were suggested. Return to work / training Relationships, childcare issues Secondary prevention – diet, exercise Psychological / emotional adaptation Stroke groups – communication support activities Support for carers Access to welfare benefits and allowances, equipment
	While the person with stroke is in hospital local processes should ensure that referral is made to adult social care for an assessment of need (if the person has a need for social care).	67	In round 2 - 19/99 (19%) panel members commented; 21/84(25%) in round 3: It was highlighted that a social worker should be part of the MDT. "at an appropriate time to allow the social worker to work alongside the MDT to fully appreciate the patient's difficulties and get to know them and their family. This shouldn't be started right at the end of the inpatient stay, but 'worked up' during the inpatient stay". Some people commented that this should be a joined up process and happen in a timely manner. "yes, prior to discharge so there is not a long gap between services

Number	Statement	Results %	Amount (No. panel members who commented / No. panel members who responded) and content of panel comments – or themes
			ending and others beginning". A couple of people commented that the statement was not very clear (for example 'local processes' was not defined and also, who would be making the assessment is unclear)

15.2.3 Delphi statement where consensus was not reached

Table 124: Table of 'non-consensus' statements with qualitative themes of panel comments

Number	Statement	Results	Amount and content of panel comments – or themes
1.	Review intervals need to be specified and agreed with the person who has had a stroke in regards to their long term rehabilitation needs.	65.0	In round 2 - 13/100 (13%) panel members commented; 9/80(11%) in round 3: Opinions were divided. Some members suggested that this should be **needs based** and **flexible** whereas others said that the **6 and 12 month follow-up was sufficient**.
2.	A review of health and social care needs of the person who has had a stroke that is formally reported and / or coordinated or conducted with the GP services should take place at least (options: 6 months, 12 months, unspecified)	44.6	In round 2 - 40/98 (41%) panel members commented; 20/83(24%) in round 3: The majority of comments stated, 6 weeks, 6 months and then annually. ("in accordance with the National Stroke Strategy @ 6/52, 6/12 then annually"). There were some comments recommending a **need based** system that would allow more frequent intervals if necessary. It was also commented that this would depend on the time post discharge. There was a concern that if it **were to be a needs based** approach people would **not be given an opportunity** for a meeting unless they have a need "If left to individual needs it tends to result in crises management

Number	Statement	Results	Amount and content of panel comments – or themes
			meetings. There should be some sort of structure and process to ensure that reviews are frequent enough to monitor the patient longer term safely and reasonably but not too frequent to be unnecessary and possibly devaluing the merit…"
3.	Where the persons who have had a stroke are still making progress likely to lead to functional change, they should be offered a goal-focused enabling care package.	56.9	In round 3 - 21/84 (25%) panel members commented; 15/72(21%) in round 4: Some people commented that this **statement was not very clear** and that the term **enabling care package** was **not universally understood**. Extract: "I suspect there will be some issues as to how you measure functional change and the word likely should there be a timescale put on this as this caveat would suggest that most patients/clients would fall into this category and services will find this very difficult to deliver…" Some comments were made about the **term 'functional change'** and that the statement was unclear about what it may be referring to.
4.	When a person with stroke leaves hospital, there should be a review of the discharge process with the person who has had a stroke together with their family and carers by a member of the community stroke rehabilitation team. The aim of this review is to ensure that the discharge plan was followed and carried out, that their current status and goals are reviewed, and a continuing rehabilitation plan is devised.	56.9	In round 2 - 22/99 (22%) panel members commented; 16/85(19%) in round 3 and 11/72 (15%) in round 4: There were some comments about the **amount of reviews** that were suggested. This should be **done according to need** since some people may be discharged and do not wish or need a post discharge meeting. "Will this apply to every stroke patient or only those discharged with a disability – I agree it should be every stroke patient but that would create a huge workload for the community stroke team … I feel that this should be reconsidered and reflect the varied post-stroke needs of patients and their carers."

Number	Statement	Results	Amount and content of panel comments – or themes
5.	Self-management and training needs form part of long term health education for the person after stroke.	61.1	In round 2 - 12/98 (12%) panel members commented; 13/84(11%) in round 3 and 9/72 (15%) in round 4: It was stated that there was **insufficient evidence** to conclude that this works. There is also the issue that it depends on **the level of post stroke ability**. "in order to support secondary prevention and more independence, education is important." "self-management isn't just about education, a person may need other interventions to facilitate behaviour change".

15.2.4 Recommendations and links to Delphi consensus survey

Statements	34. If there is a new identified need for further stroke rehabilitation services, the person who has had a stroke should be able to self-refer with the support of a GP or specialist community services. 35. Focus on life after stroke may include: • Information and discussion about community access • Participation in community activities • Social roles • Information about driving • Opportunities to discuss issues around sexual function 36. While the person with stroke is in hospital local processes should ensure that referral is made to adult social care for an assessment of need (if the person has a need for social care).
	For health and social care interface recommendations see 5.3.2. **114. Inform people after stroke that they can self-refer, usually with the support of a GP or named contact, if they need further stroke rehabilitation services.** **115. Provide information so that people after stroke are able to recognise the development of complications of stroke, including frequent falls, spasticity, shoulder pain and incontinence.** **116. Encourage people to focus on life after stroke and help them to achieve their goals. This may include:** • **facilitating their participation in community activities, such as**

	shopping, civic engagement, sports and leisure pursuits, visiting their place of worship and stroke support groups • **supporting their social roles, for example, work, education, volunteering, leisure, family and sexual relationships** • **providing information about transport and driving (including DVLA requirements; see www.dft.gov.uk/dvla/medical/aag).** **117. Manage incontinence after stroke in line with recommendations in Urinary incontinence in neurological disease (NICE clinical guideline 148) and Faecal incontinence (NICE clinical guideline 49).** **118. Review the health and social care needs of people after stroke and the needs of their carers at 6 months and annually thereafter. These reviews should cover participation and community roles to ensure that people's goals are addressed.** **119. For guidance on secondary prevention of stroke, follow recommendations in Lipid modification (NICE clinical guideline 67), Hypertension (NICE clinical guideline 127), Type 2 diabetes (NICE clinical guideline 87) and Atrial fibrillation (NICE clinical guideline 36).** **120. Provide advice on prescribed medications in line with recommendations in Medicines adherence (NICE clinical guideline 76).**
Economic considerations	There are some costs associated with the referral and with the review of health and social care needs in terms of staff time; however these interventions will also improve the quality of life of the person with stroke; an annual frequency of review (after the first review at 6 months) was considered balanced in terms of costs and effectiveness.
Other considerations	The GDG noted the different views expressed in the Delphi survey with regards being able to re-access rehabilitation services at a later time point. Some people had commented that this would create too great a demand which could not be met, while others thought the statement unclear as it implied a GP was required to make a recommendation for further services, and therefore this was not self-referral. It was thought that referral back into rehabilitation would often be after a conversation with a GP or named contact but the GDG agreed that it should be possible for a person to self-refer themselves. Information and support to enable the person and their families to readjust after what is often a life changing experience was recognised as extremely important. The GDG agreed with the comments suggesting additional areas such as information about voluntary organisations and patient groups, recognising the needs of carers etc. The variety of other examples given within the comments highlighted to the GDG that it was not possible to capture the vast range of different information needs in the wording of recommendations. It was agreed information and support is individual and providing a list of areas to include (or the professional who would be responsible to do this) was not helpful. The statement on referral to

	social care was felt to be unclear, and following consultation the GDG agreed to remove this as it was felt to be covered within the social care interface and transfer of care sections of the guideline. The GDG discussed the statement about regularly reviewing health and social care needs which did not achieve consensus. It was felt that there was disagreement about the frequency of the review rather than about whether a review should take place. The GDG agreed that opinion seemed divided on adopting a needs based approach or having a structured process determining when a review should be undertaken. The group felt it was extremely important to emphasise that reviews need to be done, in order to pick up any problems or difficulties and to highlight to both patients and their carers that this is what they should expect to happen. The GDG noted that the National Stroke Strategy recommended a review at 6 months and then annually, and that many of the comments had stated the same approach should be adopted.

16 Acronyms and abbreviations

AAT	Aachener Aphasia Test
ABMT	Abbreviated Mental Test Score
ADL	Activities of Daily Living
AFO	Ankle-Foot Orthosis
AGREE-II	Advancing Guideline Development, Reporting and Evaluation in Health Care
ANELT-A	Amsterdam Nijmegan Everyday Language Test, scale A
ANELT-A	Amsterdam-Nijmegan Everyday Language Test
APT	Attention Process Training
ARAT	Action Research Arm Test
ASCOT	Anglo-Scandinavian Cardiac Outcomes Trial
ASHA FACS	Functional Assessment of Communication Skills for Adults
BADL	Basic Activities of Daily Living
BBS	Berg Balance Scale
BIT	Behavioural Inattention Test
BNT	Boston Naming Test
CBS-WRAT	Criterion Test of Basic Skills–Wide Range Achievement Test
CES-D	Center for Epidemiologic Studies Depression Scale
CETI	Communication Effectiveness Index
CETI	Communication Effectiveness Index
CFQ	Cognitive Failures Questionnaire
CIMT	Constraint Induced Movement Therapy
CMSA	Chedoke McMaster Stroke Assessment
CMSMR	Chedoke-McMaster Stages of Motor Recovery
CNS	Central Nervous System
COAST	Communication Outcomes After Stroke scale
CPT	Continuous Performance Test
CRPS	Complex Regional Pain Syndromes
DAFO	Dynamic Ankle-Foot Orthosis
DWP	Department of Work and Pensions
EMG	Electromyography-
EQ-VAS	EuroQol Visual Analogue Scale
ESD	Early Supported Discharge
ESUS	Extended Stroke Unit Service
FAI	Frenchay Activity Index
FAST	Frenchay Aphasia Screening Test
FCP	Functional Communication Programme
FCTP	Functional Communication Therapy Planner
FCTP	Functional Communication Therapy Planner
FES	Functional Electrical Stimulation
FIM	Functional Independence Measure
FPA	Functional Communication Profile
GDS	Geriatric Depression Scale

GHQ	General Health Questionnaire
GMW	General Medical Ward
GRAFO	Ground Reaction Ankle-Foot Orthosis
HADS	Hospital Anxiety and Depression Scale
IADL	Instrumental Activities of Daily Living
ICF	International Classification of Functioning, Disability and Health
ICF	International Classification of Functioning, Disability and Health
LL-FMA	Lower limb section of the Fugl-Meyer Assessment
MAS	Motor assessment Scale
MID	Minimal Important Difference
MMSE	Mini-Mental State Examination
MOCA	Montreal Cognitive Assessment
MPCA	Measure of Participation in Conversation for Adults with Aphasia
MRC	Medical Research Council
MRW	Mixed Rehabilitation Ward
MSCA	Measure of Skill in Providing Supported Conversation for Adults with Aphasia
MUST	Malnutrition Universal Screening Tool
NAO	National Audit Office
NIHSS	National Institutes of Health Stroke Scale
OKN	Optokinetic Nystagmus
OSUS	Ordinary Stroke Unit Service
PASAT	Paced Auditory Serial Addition Test
PEG	Percutaneous Endoscopic Gastrostomy
PHQ	Patient Health Questionnaire
PICA	Porch Index of Communicative Ability
PROM	Passive Range of Mobility
PRT	Progressive Resistance Training
PSSRU	Personal Social Services Research Unit
PTH	Placebo Thermocoagulation
RPAB	Rivermead Perceptual Assessment Battery
SAD-Q	Stroke Aphasic Depression Questionnaire
SIAS	Stroke Impairment Assessment Set
SSS	Scandinavian Stroke Scale
TOM	Therapy Outcome Measure
UEFT	Upper Extremity Function Test
USN	Unilateral Spatial Neglect
WAB	Western Aphasia Battery
WAB-AQ	Western Aphasia Battery - Aphasia Quotient
WHO	World Health Organisation
WMFT	Wolf Motor Function Test
YSQ	Yale Single Question

17 Glossary

Aachener Aphasie Test (AAT)	Commonly used major comprehensive language test in German speaking countries.
Abbreviated mental test score (ABMT)	Test to assess for confusion and other cognitive impairments.
Abstract	Summary of a study, which may be published alone or as an introduction to a full scientific paper.
Action Research Arm Test (ARAT)	Observational test used to determine upper limb function.
Activities of Daily Living (ADL)	Term used in healthcare to refer to daily self-care activities within an individual's place of residence, outdoor environments, or both.
Addenbrooks Cognitive Examination	Exam which incorporates five sub-domain scores for cognition: orientation/attention, memory, verbal fluency, language and visuo-spatial.
Adjusted analysis	Usually refers to attempts to control (adjust) for baseline imbalances between groups in important patient characteristics. Sometimes used to refer to adjustments of P value to take account of multiple testing.
Allocation concealment	The process used to prevent advance knowledge of group assignment in a RCT. The allocation process should be impervious to any influence by the individual making the allocation, by being administered by someone who is not responsible for recruiting participants.
Anosognosia	A lack of awareness of impairment, not knowing that a deficit or illness exists, in memory or other function
Aphasia	Loss or impairment of the ability to use and comprehend language usually resulting from brain damage
Applicability	The degree to which the results of an observation, study or review are likely to hold true in a particular clinical practice setting.
Apraxia (of speech)	Difficulty in initiating and executing the voluntary movement needed to produce speech when there is no weakness of speech muscles. It may cause difficulty producing the correct speech or changes in the rhythm or rate of speaking.
Arm (of a clinical study)	Sub-section of individuals within a study who receive one particular intervention, for example placebo arm
Assessment	A detailed process which aims to define the nature and impact of an impairment, and devise a treatment plan.
Association	Statistical relationship between two or more events, characteristics or other variables. The relationship may or may not be causal.
Barthel Index	The Barthel Index consists of 10 items that measure a person's daily functioning, specifically the activities of daily living and mobility. The items include feeding, moving from wheelchair to bed and return, grooming, transferring to and from a toilet, bathing, walking on level surface, going up and down stairs, dressing, continence of bowels and bladder.
Baseline	The initial set of measurements at the beginning of a study (after run-in period where applicable), with which subsequent results are compared.
Basic activities of Daily Living (BADL)	List of basic activities that need to be performed independently in order for an individual to take care of himself/herself.
Beck Depression Inventory	A multiple-choice self-report inventory, used for measuring the severity of depression.
Before-and-after study	A study that investigates the effects of an intervention by measuring particular characteristics of a population both before and after taking the intervention, and assessing any change that occurs.

Berg balance scale	A widely used clinical test of a person's functional balance.
Bias	Systematic (as opposed to random) deviation of the results of a study from the 'true' results that is caused by the way the study is designed or conducted.
Blinding	Keeping some or all study participants, caregivers, researchers or outcome assessors unaware about the interventions to which the participants have been allocated in a study. See single, double and triple blinding and allocation concealment.
Boston Diagnostic Aphasia Examination	Test used to evaluate adults suspected of having aphasia
Boston Naming Test (BNT)	A confrontation naming test used to measure word retrieval performance in aphasic patients
Box and Block test	Test used to evaluate the gross manual dexterity of individuals with a physical impairment.
Brunnstrom approach	Physical therapy that emphasises the synergic pattern of movement which develops during recovery from hemiplegia. This approach encourages development of flexor and extensor synergies during early recovery, with the intention that synergic activation of muscles will, with training, transition into voluntary activation of movements.
C&E cancellation	Test used to detect the presence of unilateral spatial neglect in the near extra-personal space in patients with stroke.
Care giver burden scale	Questionnaire used to measure the subjective burden of caregivers in five domains: general strain, isolation, disappointment, emotional involvement, and environment.
Carer (caregiver)	Someone other than a health professional who is involved in caring for a person with a medical condition.
Carers strain index rankin	Is a brief, easily administered instrument which can identify strain in informal care providers. It is divided into five categories. It is a 13-question tool that measures strain related to care provision.
Cerebrovascular disease	Disease of the blood vessels supplying the brain, which may result in brain dysfunction including Stroke.
Chedoke-McMaster stages of Motion Recovery	Test used to assess the functional state of the affected upper extremity.
Clinical effectiveness	The extent to which an intervention produces an overall health benefit in routine clinical practice.
Cluster trial	A type of randomized controlled trial (RCT), in which groups or clusters of individuals rather than individuals themselves are randomized.
Cochrane Review	The Cochrane Library consists of a regularly updated collection of evidence-based medicine databases including the Cochrane Database of Systematic Reviews (reviews of randomised controlled trials prepared by the Cochrane Collaboration).
Cohort study	A retrospective or prospective follow-up study. Groups of individuals to be followed up are defined on the basis of presence or absence of exposure to a suspected risk factor or intervention. A cohort study can be comparative, in which case two or more groups are selected on the basis of differences in their exposure to the intervention of interest.
Comorbidity	Co-existence of more than one disease or an additional disease (other than that being studied or treated) in an individual.
Comparability	Similarity of the groups in characteristics likely to affect the study results (such as health status or age).
Confidence interval (CI)	A range of plausible values for the population mean (or another population parameter such as an estimation of risk increase/decrease), calculated from

	data. A confidence interval with (conventionally) a 95% confidence level has a 95% chance of capturing the population mean. This means that, if the experiment were repeated many times, 95% of the confidence intervals would contain the true population mean.
Confounding	In a study, confounding occurs when the effect of an intervention on an outcome is distorted as a result of an association between the population or intervention or outcome and another factor (the 'confounding variable') that can influence the outcome independently of the intervention under study.
Consensus methods	Techniques that aim to reach an agreement on a particular issue. Consensus methods may be used when there is a lack of strong evidence on a particular topic.
Continuous data	Data with a potentially infinite number of possible values along a continuum. Height, weight and blood pressure are examples of continuous variables.
Contralateral	On or relating to the opposite side of the body.
Contralesional	Describing the half of a patient's brain or body away from the site of a lesion.
Control group	A group of patients recruited into a study that receives no treatment, a treatment of known effect, or a placebo (dummy treatment) - in order to provide a comparison for a group receiving an experimental treatment, such as a new drug.
Cost benefit analysis	A type of economic evaluation where both costs and benefits of healthcare treatment are measured in the same monetary units. If benefits exceed costs, the evaluation would recommend providing the treatment.
Cost-consequences analysis (CCA)	A type of economic evaluation where various health outcomes are reported in addition to cost for each intervention, but there is no overall measure of health gain.
Cost-effectiveness analysis (CEA)	An economic study design in which consequences of different interventions are measured using a single outcome, usually in 'natural' units (For example, life-years gained, deaths avoided, heart attacks avoided, cases detected). Alternative interventions are then compared in terms of cost per unit of effectiveness.
Cost-effectiveness model	An explicit mathematical framework, which is used to represent clinical decision problems and incorporate evidence from a variety of sources in order to estimate the costs and health outcomes.
Cost-utility analysis (CUA)	A form of cost-effectiveness analysis in which the units of effectiveness are quality-adjusted life-years (QALYs).
Credible Interval	The Bayesian equivalent of a confidence interval.
Cross-over trial	A type of clinical trial comparing two or more interventions in which the participants, upon completion of the course of one treatment are switched to another. For example, for a comparison of treatments A and B, half the participants are randomly allocated to receive them in the order, A, B and half to receive them in the order B, A. A problem with this design is that the effects of the first treatment may carry over into the period when the second is given.
DerSimonian and Laird	A method of random effects meta-analysis (see below).
Diplopia	Double vision.
Discounting	Costs and perhaps benefits incurred today have a higher value than costs and benefits occurring in the future. Discounting health benefits reflects individual preference for benefits to be experienced in the present rather than the future. Discounting costs reflects individual preference for costs to be experienced in the future rather than the present.
Dominance	An intervention is said to be dominated if there is an alternative intervention that is both less costly and more effective.

EuroQol Visual Analogue Scale (EQ-VAS)	Quality of life measure.
Dorsiflexion	Movement which decreases the angle between the dorsum (superior surface) of the foot and the leg, so that the toes are brought closer to the shin.
Double blind	Also, Double masked. Neither the participants in a trial nor the investigators (outcome assessors) are aware of which intervention the participants are given. The purpose of blinding the participants (recipients and providers of care) is to prevent performance bias. The purpose of blinding the investigators (outcome assessors, who might also be the care providers) is to protect against detection bias. See also blinding, single blind, triple blind, and allocation concealment.
Drop-out	A participant who withdraws from a trial before the end.
Dysarthria	Difficulty in articulating words.
Dysarthrophonia	An acquired neurological speech impairment that affects respiration, production of speech sounds, articulation and intonation of speech.
Dysphagia	Difficulty in swallowing.
Dyspraxia	Difficulty in planning and executing movement
Early supported discharge	A service for people after stroke which allows transfer of care from an inpatient environment to a primary care setting to continue rehabilitation, at the same level of intensity and expertise that they would have received in the inpatient setting.
Economic evaluation	Comparative analysis of alternative health strategies (interventions or programmes) in terms of both their costs and consequences.
Edmans Activities of Daily Living Index	A graded test which assesses functional abilities in stroke patients, including the activities necessary to enable a person to live independently at home.
Effect size	1. A generic term for the estimate of effect for a study. 2. A dimensionless measure of effect that is typically used for continuous data when different scales (for example for measuring pain) are used to measure an outcome and is usually defined as the difference in means between the intervention and control groups divided by the standard deviation of the control or both groups. See standardised mean difference.)
Effectiveness	See 'Clinical effectiveness'.
Efficacy	See 'Clinical efficacy'.
EQ-5D (EuroQol-5D)	A standardised instrument used to measure a health outcome. It provides a single index value for health status.
Equinovarus	A developmental disorder of the foot in which walking is done on the toes and outer side of the sole
Errorless learning	Procedure which allows discrimination learning to occur with few or no responses to the negative stimulus.
Evidence	Information on which a decision or guidance is based. Evidence is obtained from a range of sources including randomised controlled trials, observational studies, expert opinion (of clinical professionals and/or patients).
Exclusion criteria (clinical study)	Criteria that define who is not eligible to participate in a clinical study.
Exclusion criteria (literature review)	Explicit standards used to decide which studies should be excluded from consideration as potential sources of evidence.
Extended dominance	If Option A is both more clinically effective than Option B and has a lower cost per unit of effect, when both are compared with a do-nothing alternative then Option A is said to have extended dominance over Option B.

	Option A is therefore more efficient and should be preferred, other things remaining equal.
Extrapolation	In data analysis, predicting the value of a parameter outside the range of observed values.
Follow-up	The ascertainment of outcomes of an intervention at one or more stated times after the intervention has ended.
Fixed effects meta-analysis	A fixed effect model of meta-analysis is based on a mathematical assumption that every study is evaluating a common treatment effect. That means the effect of treatment, allowing for the play of chance, was the same in all studies.
Frenchay Activities Index (FAI)	Measure of instrumental activities of daily living for use with patients recovering from stroke. This index covers a broad range of activities associated with everyday life.
Frenchay Arm Test	Test used to assess proximal control and dexterity.
Fugl-Meyer Assessment	Stroke-specific, performance-based, impairment index; designed to assess motor functioning, balance, sensation and joint functioning in hemiplegic, post-stroke patients.
Functional ambulation category	A functional walking test that evaluates ambulation ability. This 6-point scale assesses ambulation status by determining how much human support the patient requires when walking, regardless of whether or not they use a personal assistive device
Functional ambulation classification	Assesses functional mobility and gait in patients undergoing physical therapy.
Functional Assessment of Communication Skills for Adults (ASHA FACS),	This assessment assists with measuring and recording the functional communication of adults with speech, language, and cognitive communication disorders. It assesses functional communication in four areas: social communication; communication of basic needs; reading, writing, and number concepts; and daily planning.
Functional Independence Measure (FIM)	Scale used to measure the functional abilities of patients undergoing rehabilitation.
Generalisability	The extent to which the results of a study based on measurement in a particular patient population and/or a specific context hold true for another population and/or in a different context. In this instance, this is the degree to which the guideline recommendation is applicable across both geographical and contextual settings. For instance, guidelines that suggest substituting one form of labour for another should acknowledge that these costs might vary across the country.
Geriatric depression scale	This is suitable as a screening test for depressive symptoms in the elderly; ideal for evaluating the clinical severity of depression.
Global Nottingham Health Profile 1&2	Patient-completed two-part questionnaire designed to determine and quantify perceived health problems. Part one covers 6 areas (sleep, mobility, energy, pain, emotional reactions, social isolation); and part two covers specific aspects of daily life (employment, household chores, social life, relationships, sex life, hobbies, holidays).
GRADE / GRADE profile	A system developed by the GRADE Working Group to address the shortcomings of present grading systems in healthcare. The GRADE system uses a common, sensible and transparent approach to grading the quality of evidence. The results of applying the GRADE system to clinical trial data are displayed in a table known as a GRADE profile.
Habitual Gait Velocity	Also known as comfortable gait speed, it is defined as a person's usual or comfortable, self-selected pace.
Hand grip force	The strength applied by the hand to pull on or suspend from objects and is a specific part of hand strength.

Harms	Adverse effects of an intervention.
Health economics	The study of the allocation of scarce resources among alternative healthcare treatments. Health economists are concerned with both increasing the average level of health in the population and improving the distribution of health.
Health-related quality of life (HRQoL)	A combination of an individual's physical, mental and social well-being; not merely the absence of disease.
Hemiagnosia	Inability of a person to process and perceive stimuli on one side of the body or environment that is not due to a lack of sensation – a deficit in attention to and awareness of one side of space is observed.
Hemianopia	Blindness in one half of the visual field of one or both eyes.
Hemineglect	See Hemiagnosia
Hemiparesis	Weakness on one side of the body.
Hemiparetic	Pertaining to hemiparesis or a patient affected with hemiparesis.
hemiplegia	Total paralysis of the arm, leg, and trunk on one side of the body.
Hemispatial neglect	See Hemiagnosia
Heterogeneity Or lack of homogeneity.	The term is used in meta-analyses and systematic reviews when the results or estimates of effects of treatment from separate studies seem to be very different – in terms of the size of treatment effects or even to the extent that some indicate beneficial and others suggest adverse treatment effects. Such results may occur as a result of differences between studies in terms of the patient populations, outcome measures, definition of variables or duration of follow-up.
Imprecision	Results are imprecise when studies include relatively few patients and few events and thus have wide confidence intervals around the estimate of effect.
Inclusion criteria (literature review)	Explicit criteria used to decide which studies should be considered as potential sources of evidence.
Incremental analysis	The analysis of additional costs and additional clinical outcomes with different interventions.
Incremental cost	The mean cost per patient associated with an intervention minus the mean cost per patient associated with a comparator intervention.
Incremental cost effectiveness ratio (ICER)	The difference in the mean costs in the population of interest divided by the differences in the mean outcomes in the population of interest for one treatment compared with another.
Indirectness	The available evidence is different to the review question being addressed, in terms of PICO (population, intervention, comparison and outcome).
Instrumental Activities of Daily Living (IADL)	List of activities which allows an individual to live independently in a community: housework, meal preparation, taking medications, managing money, shopping for groceries or clothing, telephone use and if applicable, the use of technology.
Intention to treat analysis (ITT)	An intention-to-treat analysis is one in which all the participants in a trial are analysed according to the intervention to which they were allocated, whether they received it or not. Intention-to-treat analyses are favoured in assessments of effectiveness as they mirror the non-compliance and treatment changes that are likely to occur when the intervention is used in practice and because of the risk of attrition bias when participants are excluded from the analysis.
Intermediate Outcome	A measure of results that indicates progress toward desired end results but is not itself a final outcome.
Interphalangeal	Between the phalanges.

Intervention	Healthcare action intended to benefit the patient, for example, drug treatment, surgical procedure, psychological therapy.
Inverse variance	A method of aggregating two or more random variables to minimize the variance of the sum. Each random variable in the sum is weighted in inverse proportion to its variance. We could assume that variance is inversely proportional to importance, i.e. the less variance in the study, the more weight it should contribute. The Inverse Variance method in RevMan (see below), calculates study weights directly based on this assumption.
Ipsilateral	On or relating to the same side (of the body)
Isometric elbow extension force	The force used when attempting to extend the elbow against resistance. Isometric implies no actual movement is made.
Isometric elbow flexion force	The force used when attempting to bend the arm at the elbow against resistance. Isometric implies no actual movement is made.
IVA-Continuous Performance Test - Full Scale Attention Quotient	Test used to measure auditory and visual reaction time and stability, simultaneously, not separately.
Jebsen-Taylor Hand function test	Test designed to provide a short, objective test of hand functions commonly used in activities of daily living (ADLs). The target patient population includes adults with neurological conditions involving hand disabilities. The test was developed to be used by health professionals working in restoration of hand function.
Knee extension peak torque	Measurement of the person's ability to flex the quadriceps muscles which straighten the leg.
Knee flexion peak torque	Sit-and-reach test used to test flexibility.
Length of stay	The total number of days a participant stays in hospital.
Life-years gained	Mean average years of life gained per person as a result of the intervention compared with an alternative intervention.
Likelihood ratio	The likelihood ratio combines information about the sensitivity and specificity. It tells you how much a positive or negative result changes the likelihood that a patient would have the disease. The likelihood ratio of a positive test result (LR+) is sensitivity divided by 1- specificity.
Line Bisection	Quick measure to detect the presence of unilateral spatial neglect.
Line bisection task	Standard assessment of unilateral visual neglect.
Locus of Control Scale	Refers to the extent to which individuals believe that they can control events that affects them.
Long-term care	Residential care in a home that may include skilled nursing care and help with everyday activities. This includes nursing homes and residential homes.
Loss to follow-up	Loss of contact with some participants, so that researchers cannot complete data collection as planned. Loss to follow-up is a common cause of missing data, especially in long-term studies and can cause bias when subjects lost from a cohort have different health response distributions from subjects who remain in follow-up
Mantel Haenszel approach	A method to analyse odds ratios that has been extended to analyse risk ratios and risk differences. It assumes a fixed effect and combines studies using a method similar to inverse variance approaches to determine the weight given to each study.
Markov model	A method for estimating long-term costs and effects for recurrent or chronic conditions, based on health states and the probability of transition between them within a given time period (cycle).
Maximal Gait Velocity	Also known as fast gait speed, it is defined as the speed a person's fast as safely possible, self-selected pace.
McKenna Graded Naming	Test used to assess object-naming ability, but is in addition graded in

Test	difficulty to allow for individual differences. This means that it may be able to detect any word-finding difficulty even in those with an extensive naming vocabulary.
Measurement	the use of psychometrically robust tools to record the extent of a problem, whether it is impairment, activity or participation based and can be generic or disease specific.
Mean	The average value, calculated by adding all the observations and dividing by the number of observations.
Median	The numerical value separating the higher half of a sample, a population, or a probability distribution, from the lower half. The median of a finite list of numbers can be found by arranging all the observations from lowest value to highest value and picking the middle one. If there is an even number of observations, then there is no single middle value; the median is then usually defined to be the mean of the two middle values.
Medical Research council Scale (MRC Scale) for Muscle strength	Scale for assessing muscle weakness/strength.
Mesulam Verbal Cancellation Test	Test used to evaluate hemispatial dominance in Stroke Patients.
Meta-analysis	A statistical technique for combining (pooling) the results of a number of studies that address the same question and report on the same outcomes to produce a summary result. The aim is to derive more precise and clear information from a large data pool. It is generally more reliably likely to confirm or refute a hypothesis than the individual trials.
Minimal Important Differences (MID)	For continuous outcomes, the MID is defined as “the smallest difference in score in the outcome of interest that informed patients or informed proxies perceive as important, either beneficial or harmful, and that would lead the patient or clinician to consider a change in the management (refs). An effect estimate larger than the MID is considered to be “clinically important”. For dichotomous outcomes the MID is the smallest decrease or increase is the incidence of an outcome that would be considered to show a clear appreciable benefit or harm from an intervention this can be considered in relative terms (using the risk ratio) but preferably should be based on absolute risk differences.
Mnemonic strategies	Systematic strategies for strengthening long-term retention and retrieval of information.
Modified Ashworth Scale	This scale measures resistance during passive soft-tissue stretching.
Modified rankin	A commonly used scale for measuring the degree of disability or dependence in the daily activities of people who have suffered a stroke.
Motricity Index	Staff-completed index of limb movement aiming to measure general motor impairment. Three movements for each limb are assessed based on the Medical Research Council strength grades and weighted, zero for no movement, nine for palpable movement, fourteen for movement seen, nineteen for full range against gravity, twenty-five for movement against resistance and twenty-two for normal power.
Neglect	Inability to orient towards and attend to stimuli, including body parts, on the side of the body affected by the stroke.
Neuroplasticity	Structural and functional changes to the brain and nervous system as a result of input from the environment.
Neuropsychological	Related to the structure and function of the brain specific to psychological processes and behaviours.
Non-paretic	Usually refers to the un-affected limb

Nottingham Extended Activities of Daily Living	Self-report scale designed primarily for use in the stroke population for functional assessment.
Observational study	Retrospective or prospective study in which the investigator observes the natural course of events with or without control groups; for example, cohort studies and case–control studies.
Opportunity cost	The loss of other health care programmes displaced by investment in or introduction of another intervention. This may be best measured by the health benefits that could have been achieved had the money been spent on the next best alternative healthcare intervention.
Orthosis	A device that supports or corrects the function of a limb or the torso.
Orthotics	Specialty within the medical field concerned with the design, manufacture and application of orthoses. An orthosis (plural: orthoses) is an orthopaedic device that supports or corrects the function of a limb or the torso.
Outcome	Measure of the possible results that may stem from exposure to a preventive or therapeutic intervention. Outcome measures may be intermediate endpoints or they can be final endpoints. See 'Intermediate outcome'.
Palmar grip torque	Palmar grip torque is a measurement of the ability to hold larger and heavier objects such as cans and bottles between the palm of the hand and the four fingers.
Perimetry	A way to systematically test, used to map and quantify the visual field, especially at the extreme periphery of the visual field. The name comes from the method of testing the perimeter of the visual field.
Pinch grip force	The strength applied by the hand to pinch an object so that the fingers are on one side of the object, and the thumb is on the other. Typically, an object lifted in a pinch grip does not touch the palm.
Placebo	An inactive and physically identical medication or procedure used as a comparator in controlled clinical trials.
Power (statistical)	The ability to demonstrate an association when one exists. Power is related to sample size; the larger the sample size, the greater the power and the lower the risk that a possible association could be missed.
Pre-test probability	For diagnostic tests. The proportion of people with the target disorder in the population at risk at a specific time point or time interval. Prevalence may depend on how a disorder is diagnosed.
Primary care	Healthcare delivered to patients outside hospitals. Primary care covers a range of services provided by general practitioners, nurses, dentists, pharmacists, opticians and other healthcare professionals.
Primary outcome	The outcome of greatest importance, usually the one in a study that the power calculation is based on.
Prism glasses	Medical device used in correcting eye abnormalities.
Prognosis	A probable course or outcome of a disease. Prognostic factors are patient or disease characteristics that influence the course. Good prognosis is associated with low rate of undesirable outcomes; poor prognosis is associated with a high rate of undesirable outcomes.
Proprioceptive	Individual's sense of the relative position of neighbouring parts of the body.
Prospective study	A study in which people are entered into the research and then followed up over a period of time with future events recorded as they happen. This contrasts with studies that are retrospective.
Psychometric	Related to the theory and technique of educational measurement and psychological measurement, which includes the measurement of knowledge, abilities, attitudes, and personality traits.
Publication bias	Also known as reporting bias. A bias caused by only a subset of all the relevant data being available. The publication of research can depend on the

	nature and direction of the study results. Studies in which an intervention is not found to be effective are sometimes not published. Because of this, systematic reviews that fail to include unpublished studies may overestimate the true effect of an intervention. In addition, a published report might present a biased set of results (for example only outcomes or sub-groups where a statistically significant difference was found.
P-value	The probability that an observed difference could have occurred by chance, assuming that there is in fact no underlying difference between the means of the observations. If the probability is less than 1 in 20, the P value is less than 0.05; a result with a P value of less than 0.05 is conventionally considered to be 'statistically significant'.
Quadrantanopia	Refers to loss of vision affecting a quarter of the field of vision. It can be associated with a lesion of an optic radiation.
Quality of life	See 'Health-related quality of life'.
Quality-adjusted life year (QALY)	An index of survival that is adjusted to account for the patient's quality of life during this time. QALYs have the advantage of incorporating changes in both quantity (longevity/mortality) and quality (morbidity, psychological, functional, social and other factors) of life. Used to measure benefits in cost-utility analysis. The QALYs gained are the mean QALYs associated with one treatment minus the mean QALYs associated with an alternative treatment.
Quasi-randomised trial	A trial using a quasi-random method of allocating participants to different forms of care. There is a greater risk of selection bias in quasi-random trials where allocation is not adequately concealed compared with randomised controlled trials with adequate allocation concealment.
Quick Reference Guide	An abridged version of NICE guidance, which presents the key priorities for implementation and summarises the recommendations for the core clinical audience.
Random effects meta-analysis	The random effects model assumes that the true treatment effects in the individual studies may be different from each other. That means there is no single number to estimate in the meta-analysis, but a distribution of numbers. The most common random effects model also assumes that these different true effects are normally distributed. The meta-analysis therefore estimates the mean and standard deviation of the different effects.
Randomisation	Allocation of participants in a research study to two or more alternative groups using a chance procedure, such as computer-generated random numbers. This approach is used in an attempt to ensure there is an even distribution of participants with different characteristics between groups and thus reduce sources of bias.
Randomised controlled trial (RCT)	A comparative study in which participants are randomly allocated to intervention and control groups and followed up to examine differences in outcomes between the groups.
RCT	See 'Randomised controlled trial'.
Relative risk (RR)	The number of times more likely or less likely an event is to happen in one group compared with another (calculated as the risk of the event in group A/the risk of the event in group B).
Reporting bias	See publication bias.
Resource implication	The likely impact in terms of finance, workforce or other NHS resources.
Retrospective study	A retrospective study deals with the present/ past and does not involve studying future events. This contrasts with studies that are prospective.
Review question	In guideline development, this term refers to the questions about treatment and care that are formulated to guide the development of evidence-based recommendations.
Rey-Osterreith Test	Neuropsychological assessment in which examinees are asked to reproduce a

	complicated line drawing, first by copying and then from memory.
Rivermead ADL	Scale developed to assess activities of daily living in stroke patients.
Rivermead Mobility Index	Measure of disability related to bodily mobility. It demonstrates the patient's ability to move her or his own body.
Rivermead Perceptual Assessment Battery (RPAB)	Preliminary assessment of one's level of visual perceptual ability prior to therapy. The results may be used to plan an appropriate therapy programme.
Screening	A process of identifying people with particular impairments. People can then be offered information, further assessment and appropriate treatment. Screening may be performed as a precursor to more detailed assessment.
Search strategy	The methods used to identify studies including hand-searching relevant journals, searching electronic databases, contacting drug companies, other forms of personal contact and checking reference lists.
Secondary outcome	An outcome used to evaluate additional effects of the intervention deemed a priori as being less important than the primary outcomes.
Selection bias	A systematic bias in selecting participants for study groups, so that the groups have differences in prognosis and/or therapeutic sensitivities at baseline. Randomisation (with concealed allocation) of patients protects against this bias.
Short Form-36 (SF 36)	Multi-purpose, short-form health survey with thirty-six questions. It yields an eight-scale profile of functional health and well-being scores as well as psychometrically-based physical and mental health summary measures and a preference-based health utility index.
Significance (clinical)	In medicine and psychology, this refers to either of two related but slightly dissimilar concepts whereby certain findings or differences, even if measurable or statistically confirmed, either may or may not have additional significance, either by (1) being of a magnitude that conveys practical relevance (a usage that conflates practical and clinical significance interchangeably), or (2) more technically and restrictively, addresses whether an intervention or treatment may or may not fully correct the finding.
Significance (statistical)	A result is deemed statistically significant if the probability of the result occurring by chance is less than 1 in 20 ($p < 0.05$).
Single blind	Also, single masked. The investigator is aware of the treatment/intervention the participant is getting, but the participant is unaware. See also blinding, double blind, triple blind.
Spasticity	Muscular hyper tonicity with increased tendon reflexes
Spatial neglect	See Hemiagnosia
Stakeholder	Those with an interest in the use of the guideline. Stakeholders include manufacturers, sponsors, healthcare professionals, and patient and carer groups.
Standardised mean difference	The difference between two means divided by an estimate of the within-group standard deviation. When an outcome (such as pain) is measured in a variety of ways across studies (using different scales) it may not be possible directly to compare or combine study results in a systematic review. By expressing the effects as a standardised value the results can be combined since they have no units. Standardised mean differences are sometimes referred to as a d index.
Statistical power	The probability that the null hypothesis will be rejected if it is indeed false. In studies of the effectiveness of healthcare interventions, power is a measure of the certainty of avoiding a false negative conclusion that an intervention is not effective when in truth it is effective. The power of a study is determined by how large it is (the number of participants), the number of events (for example strokes) or the degree of variation in a continuous outcome (such as weight), how small an effect one believes is important (i.e. the smallest

	difference in outcomes between the intervention and the control groups that is considered to be important), and how certain one wants to be of avoiding a false positive conclusion (i.e. the cut-off that is used for statistical significance).
Strength and finger extension	Measurement of the strength used to open the hand, stretching all the fingers.
Stroke Self-Efficacy Questionnaire	Questionnaire used to measure self-efficacy judgements in specific domains of functioning relevant to individuals following stroke.
Stroke impact scale	Stroke-specific, self-report, health status measure, designed to assess multidimensional stroke outcomes, including strength, hand function, activities of daily living/instrumental activities of daily living, mobility, communication, emotion, memory and thinking, and participation.
Stroke Unit	An environment in which multidisciplinary stroke teams deliver stroke care in a dedicated ward which has a bed area, dining area, gym, and access to assessment kitchens.
Stroke Rehabilitation Service	A stroke service designed to deliver stroke rehabilitation either in hospital or in the community.
Stroke Service	A service designed to deliver a range of activities including assessment in casualty, delivery of acute care, follow-up of outpatient review, community services.
Stroke unit	An environment in which multidisciplinary stroke teams deliver stroke care in a dedicated ward which has a bed area, dining area, gym, and access to assessment kitchens.
Stylus maze test	Spatial memory task thought to be sensitive to frontal and parietal damage.
Systematic review	Research that summarises the evidence on a clearly formulated question according to a pre-defined protocol using systematic and explicit methods to identify, select and appraise relevant studies, and to extract, collate and report their findings. It may or may not use statistical meta-analysis.
Tangent Screen Examination	Visual field test used to analyse a patient's visual field.
The Paced Auditory Serial Addition Test (PASAT)	Measure of cognitive function that specifically assesses auditory information processing speed and flexibility, as well as calculation ability.
Time horizon	The time span over which costs and health outcomes are considered in a decision analysis or economic evaluation.
Transcranial Magnetic Stimulation (TMS)	Non-invasive method that uses electromagnetic induction to induce weak electric currents using a rapidly changing magnetic field allowing the functioning and interconnections of the brain to be studied.
Treatment allocation	Assigning a participant to a particular arm of the trial.
Unilateral neglect	See Hemiagnosia
Univariate	Analysis which separately explores each variable in a data set.
Utility	A measure of the strength of an individual's preference for a specific health state in relation to alternative health states. The utility scale assigns numerical values on a scale from 0 (death) to 1 (optimal or 'perfect' health). Health states can be considered worse than death and thus have a negative value.
Visual Analogue Mood Scale	Scale used to measure the internal mood state in neurologically impaired patients.
Wechsler Adult Intelligence Scale Revised Digit Span	Primary clinical instrument used to measure adult and adolescent intelligence; it consists of six verbal and five performance subtests. The verbal tests are: Information, Comprehension, Arithmetic, Digit Span, Similarities, and Vocabulary. The Performance subtests were: Picture Arrangement, Picture Completion, Block Design, Object Assembly, and Digit Symbol. Verbal, performance and full scale Intelligence Quotient scores were also obtained.

Wechsler memory scale	Test designed to measure different memory functions in a person.
Western Aphasia Battery (WAB)	Instrument used to assess the language function of adults, able to discern the presence, degree, and type of aphasia.
Wiener Determinationsgerat	Computer assisted reaction training, which measures alertness.
Wolf Motor Function Test (WMFT)	Test used to quantify upper extremity motor ability through timed and functional tasks.
Wunndt-Jastrow Issusion and reading	Test used to assess neglect.
Yale Single Question (YSQ)	Assessment used for depression that entails asking patients the Yale Single Question: 'Do you frequently feel sad or depressed?'
Zahlen-Verbindungs Test	German language-free intelligence test, that uses number connection tests to assess participants.

18 Reference list

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